THE PLACEBO EFFECT

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Asbjorn Hrobjartsson

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The Placebo effect

- a therapeutical phenomenon between science & humanities, body & mind.

Why do doctors begin by practising on the credulity of their patients with so many false promises of a cure, if not to call the power of the imagination ...? They know ... that there are men on whom the mere sight of medicine is operative.

Montaigne[1]

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1 Montaigne, Michel Eyquem. In Essays: "On The Power of the Imagination". Penguin Classics. Bungey, Suffulk 1981: p.44

Introduction

A Clinical example

Mr. Walker had a pain in the back. It had bothered him before, and the doctors he had consulted had given him analgesics, prescribed massage and even made him do push-ups in a gym. Nothing had helped. He had heard that his new physician, Dr. Pascal, could do wonders. Well, that was at least what Mrs. Watson said, and she used to have lots of troubles with her own back.

After waiting the usual hour Mr. Walker entered the consultation room. He explained his story. Dr. Pascal listened carefully and asked detailed questions about when, where and how his back hurt. Suddenly Mr. Walker found himself explaining things that he had never before told a doctor. They were usually so quick to prescribe, that one hardly got the chair warmed up before one was outside again fumbling with the prescription. After twenty minutes Dr. Pascal looked at him and with a self-confident voice said: "I have a cure for your problem". He reached for a syringe and filled it with medicine from an impressive looking red bottle. He concentrated on

its content as he eased out some drops that appeared to be superfluous, while at the same time saying: " this might hurt a bit in the beginning, but that is just because it is such a strong medicine. It´ll get your back better again". Then he injected the medicine. The injection did hurt, but Mr. Walker soon forgot it when Dr. Pascal asked him to see him again in a week just to confirm the improvement.

A week later Mr. Walker´s back pain was much better. He saw Dr. Pascal, who smiled an enigmatic smile. An injection of the powerful medicine was repeated, and Mr. walker went home again.

Later that afternoon the physician sat in front of his desk looking with contemplation at the red bottle of medicine. Approximately at the same time Mr. Walker was playing football for the first time in months. Dr. Pascal opened the bottle and inspected the colourless contents. He was a successful doctor thanks to that medicine. The thing that only he knew was that the liquid so resembling a panacea was nothing but salt water. His face showed an expression of slight wondering. "A placebo is a strange thing" he thought. His speculation was interrupted by the knocking on the door and he quickly transformed into his usual calmness, as he opened the door for his next patient: Mrs. Watson...

What Dr. Pascal was prescribing is called a placebo, a medicine that has no pharmacological effect. The improvement of Mr. Walker´s back pain is the effect of a placebo and is called a placebo effect.

Dr. Pascal is derived from the character in the novel by Emile Zola bearing the same name[2]. The novel is about a physician who thinks he has invented a panacea, but realises to his astonishment that an injection of salt water has the same effect on his patients. Zola is describing an example of the placebo effect.

Methodology

This thesis is part of an emerging subdivision of the field of philosophy known as the philosophy of medicine. Medicine gains from the philosophical approach to its fundamental concepts and routines. Philosophical analysis has already shown itself to be fruitful in the field of medical ethics. However, I am also quite certain that philosophy as such can gain much from focusing on medicine. There is in the theory of knowledge a strange reluctance to look further than to mathematics and physics for examples and inspiration. I believe, as well, that metaphysics can discover new versions of old problems relating to fundamentals such as life, death, nature, truth and normality. Sometimes it is discussed whether philosophy of medicine is fundamentally a philosophical or a medical discipline. Such a discussion is rather futile, but possibly indicates a methodological uncertainty: how are the problems of philosophy of medicine to be approached. A reasonable first answer to such a question is that the method is philosophical but the subject matter is medical. Though basically a good division of labour I think that if philosophy of medicine in the future is to be accepted as an autonomous academical discipline a more detailed

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2 Zola, Emile. Le Docteur Pascal. Paris: NRF, 1986 (La Pléiade, vol. 5).

and structured methodological discussion is necessary. The method of this thesis is fundamentally philosophical. The discussions that I engage in and the concepts that I make use of are for the most part established philosophical terminology and problems. However, the medical dimension is not totally restricted from the methodological approach. Firstly I consider the placebo effect, not only as an academical concept, but also as a therapeutical notion. From a medical methodological perspective the therapeutical implications of a research subject matter cannot be omitted. The second medical methodological feature that I emphasise is the approach to the substantiation of the placebo effect. A classical philosophical analysis of the subject would probably accept the standard medical description of the phenomenon and regard it as a foundation on which the discussion is built. A critical approach to the articles that substantiate the range and structure of the placebo effect does not only reflect medical problems regarding clinical research methodology, but also have implications to the philosophical problems, for example, regarding defining the placebo effect. In general a more critical approach to the empirical phenomenon founding a philosophical analysis could be one of the medical aspects of a future methodology of philosophy of medicine, a methodology that is more subtle than an automatic application of philosophical problems.

The range of the field of medical philosophy is as uncertain as its methodology, but one academical pursuit has in the last decades established itself as the most important: medical ethics. It is so dominant in medical philosophy that I find it necessary to make explicit why I do not engage in a medical ethical analysis of the

placebo effect. One of the reasons is that medical ethics is already a recognized synthesis of medicine and philosophy, and also in the specific field of placebo much attention has been focused on the moral implications of placebo controlled trials and placebo prescriptions. I would like to promote a broader field of medical philosophy, where epistemology and metaphysics are just as natural to engage in as ethics. Another reason is that ethical dilemmas sometimes resolve themselves once they are realised as conflicts whose nature is either empirical or metaphysical. Without asserting that this is the case with placebo, I am convinced that an ethical analysis could gain precision from a metaphysical and epistemological basis.

Investigation Demarcation

The thesis is constructed as consisting of two phases. Beside a general introduction and a conceptual analysis, it is divided in two sections, the first is an analysis of the implication of placebo effect on scientific medicine, the second is an analysis of the implication of the placebo effect on the mind-body problem. In some respects the two approaches to the placebo effect are rather separate, one being predominantly epistemological and the other metaphysical. However, theory of medical science and the mind-body problem are thematically intimately connected. For example in the mind-body discussion the materialists emphasise that a *scientific* world view is lost if one accepts a dualistic position. The classical Cartesian conception of mind and body operated with a deterministic *causality* notion. Last but not least, one of the most important

problematic fields of contemporary medicine is the role of the *psyche* or the mind in relation, not only to disease, but also to therapy. I could have chosen to fit in the necessary mind-body discussions in a predominantly epistemological analysis, or the other way around, fitted the most important medical scientific concepts to the mind-body problem. However, to focus on one level of discussion, for example epistemological, would mean treating important problems, like the complexity of mind-body interaction superficially. The placebo effect is a phenomenon that is ubiquitous to such a degree that a predominant epistemological or ontological analysis would be insufficient. Instead I have chosen a two legged disposition where the epistemological and mind-body approach to the placebo effect are treated consecutively. With this construction the two approaches mutually support each other, while still individually represent comprehensible analyses.

That a pharmacologically inert pill can change symptoms and influence bodily disease is a phenomenon conflicting with a normal conception of the nature of both medical science and the relation between body and mind. How does the placebo effect fit with scientific medicine? Is it a phenomenon that contrasts with the scientific biological framework of medicine or is it possible to integrate the placebo effect within this framework? In an analysis of the role of the placebo effect within the medical scientific framework I will focus on an apparent self-contradiction. The placebo effect is simultaneously regarded as a central concept in clinical investigation, and in other contexts is frowned upon as an unreal and peripheral phenomenon. With a theory of science approach to the placebo effect I will partly illustrate the limits of

important concepts that serve as a foundation for scientific medicine, and as well, provide notions that are necessary for the characterisation and analysis of such a puzzling and provocating phenomenon as the placebo effect.

How can a patient's interpretation of a clinical situation affect bodily functions, symptoms and diseases? The metaphysical problem of the status of the mind and its eventual interaction with the body can fruitfully be approached from a medical angle. The placebo effect is an example of a very special interaction between mind and body. Normally mind-body interactions in medicine are physiological or pathological. But that the mind is able, not only to decide to move the body, but actually therapeutically affects and cures diseases is new. What implications does the placebo effect have on the most important mind-body theories? Is it possible to integrate the placebo effect in a theory of mind?

The placebo effect is an intriguing phenomenon that is placed in a field of tension between subject and object, between body and mind. The eight chapters of the thesis contain different analyses of how this field of tension is constructed and its relation to the placebo effect . The problem I intend to investigate is : What are the implications of the placebo effect on the Scientific Medical Model, and in continuation, what implications does the placebo effect have for the mind-body problem?

Disposition

The thesis is constructed in three main parts, each focusing on respectively general, epistemological and metaphysical aspects of the placebo effect. The first part aims at answering the question: *"What is a placebo and what is the placebo effect?"* and includes chapters one and two. The first chapter is a broad introduction and the second is an analysis of placebo definitions.

The second part of the thesis concerns itself with the theory of medical knowledge, and intends to answer the question: *"What implications does placebo have on the scientific medical model?"* and contains chapters three to six. Chapter three is a discussion about the notion of medical models, chapter four contrasts the placebo effect with the Bio-mechanical position while chapter five contrasts the placebo effect with the empirical position. The final chapter in the second part of the thesis is a broad hermeneutical approach with the intention of contrasting it with the scientific model and providing a hypothesis concerning the causal mechanisms of the placebo effect.

The third part offers a metaphysical approach and is intended to answer the question: *"What implications does the placebo effect have for the mind-body problem?"* The final part consists in chapters seven and eight. Chapter seven is a discussion of the general theories of mind and their applicability on medicine and the placebo effect. In chapter eight I focus on a specific theory of mind, biological naturalism, and discuss whether it can provide a philosophical framework for the placebo effect.

Chapter one:

What is this thing called placebo?

The etymology of the word "placebo"

Today placebo is mostly associated with medicine, but originally "placebo" was a clerical expression. "Placebo" derives from the vulgar Latin verb "placere", meaning to please (it is the first person singular of the future indicative). It can be traced back to the 116th psalm´s ninth verse, which begins with: Placebo Domino in regio vivorum, meaning "I shall please The Lord in the land of the living". The Latin text is a translation from the Greek Septuagint Bible. Here the verse started with "euarestiso" (to please), which is rather misleading as the Hebrew original text uses "et-ha-lach", meaning I shall walk. It is believed that the Greek translator made an error. Regardless of this the psalm was sung in its Latin version in the

thirteenth century as vespers for the dead in the Catholic services, and soon "placebo" entered English as the common name for the vespers[3],[4].

Some centuries later placebo took on a derivative secular meaning as a term for professional mourners who sang placebos, instead of or with the family but, in addition, acquired a more general and negative meaning as a servile toady. It was also used as a synonym for a sycophant, flatterer or parasite.

It was not until 1785 that the term entered the formal medical vocabulary. Motherby's New Medical Dictionary from that year defines placebo as *"a commonplace method or medicine"*. The 1795 edition includes as well "calculated to amuse for a time, rather than for any other purpose". In 1811 the last feature had taken over, and placebo is in Hooper's Medical Dictionary described as *"an epithet given to any medicine adopted to please rather than to benefit the patient"*. A modern dictionary quotation reflects the changes since the early nineteenth century. Dorland's Medical Dictionary from 1988 describes placebo as *".. any dummy medical treatment; originally a medical preparation having no specific pharmacological activity against the patient's illness... More recently a dummy treatment administered to the control group in a controlled clinical trial..."*

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3 Shapiro, AK. A Contribution to the History of the Placebo Effect. Behavioural Science 1960;5:115.

4 Lasagna, L. The Placebo Effect. J. Allergy Clin. Immunol. 1986;78(1):161.

The Characteristic features of Placebos and the Placebo Effect

In many discussions about the placebo effect, including the present one, the placebo prescription often takes the form of a pharmacological inert pill. The focus on the placebo as a pill is reasonable insofar as most placebo prescriptions actually are given as pills. Possibly the emphasis on placebo pills also serves a heuristic purpose. Except for special metabolic disorders, for example diabetes, it is extremely unlikely that the content of the typical placebo pill, sugar, has any hidden pharmacological effects explaining its therapeutical success. This is less clear with respect to other forms of placebos. Bretlau[5] expresses doubt in an article about placebo effect in surgery for Meniere's disease whether he is describing a placebo effect or a unknown specific effect. The high effect rates (70 %) in both control and treatment group could be explained by an unknown effect of mastoidectomy on the inner ear. However, despite the heuristic and statistical reasons for focusing on placebo as pills it is important to emphasize that other medical manipulations can cause a placebo effect as well. Injections or surgery can act as placebos, but also being hospitalised or even the fact of being on a waiting list for a psychiatric interview have been reported to cause placebo effects.[6] In principle any kind of medical manipulation has the potential to cause a placebo effect. Brody[7] claims the different placebo treatment types can be placed in a hierarchical order after their potency: surgery is as placebo more

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5 Bretlau, P. et al. Placebo effect in surgery for Meniere's disease: nine-year follow-up. The American Journal of Otology 1989;10(4):259-261.

6 Brody, H. Placebos and the Philosophy of medicine. The University of Chicago Press. Chicago and London 1980: p.11.

7 Ibid: p. 14

effective than an injection. An injection is more potent than a pill. Huskinson even ascribes the colour of the pill an importance, red pills have been shown to be more important than for example white[8].

If any kind of medical manipulation can cause a placebo effect, what about the diseases in question: can a placebo effect influence all kind of disorders? The general nature of the placebo effect is illustrated by the fact that almost every kind of symptoms and disease have been reported as influenced by a placebo. One list of conditions relieved by placebo include cough, mood changes, angina pectoris, headache, seasickness, anxiety, hypertension, status asmaticus, depression and common cold[9]. Shapiro adds "organic illnesses, including incurable malignancies"[10]. However, despite its very general influence, there are certain conditions where placebos have been reported more frequently and with higher effect rates. Possibly the most important of these conditions is pain. The literature on placebo's influence on pain is one of the most well researched. Another type of diseases prone to a high placebo response rate is chronic disorders with cyclic pattern as for example chronic migraine or ulcer. A third type is psychosomatic diseases. Beecher[11] has done an influential review of the response rates of placebo treatment and concludes that the response rate is typically around 35 %, meaning that about one out of three patients will respond to a placebo treatment. The degree of respond vary

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8 Huskinson. Simple Analgesics for Arthritis. Br. Med. J. 1974;4:196-200.

9 See note 4: p. 14

10 Shapiro, AK. The placebo respons. In Modern perspectives in world psychiatry, ed. Howells, JG. Oliver & Boyd. Edinburgh 1968.

11 Beecher, H. The Powerful Placebo. JAMA 1955;17:1602-6.

from a noticeable effect to a full recovery. Finally it is important to distinguish between "positive" and "negative placebo" effects. A positive placebo has therapeutical effects. A negative placebo, also called "nocebo", enhances symptoms. Headache, pain, arterial hypotension, urticaria and other symptoms have been reported as a consequence of a nocebo prescription.[12]

Are there any detectable difference between the patients that respond to a placebo and those who do not? The search for the "placebo receptor personality" has been on the agenda for many years. The hope was to detect some personality features that enabled a researcher to predict with a reasonable level of certainty who would respond to a placebo and who not. The project has not been very successful. There is no stability in the placebo responses. A patient who responds on one occasion might possible not do so later, and another patient who was not effected by a placebo, might possibly react later. There is very little correlation between personality type and placébo effect. However, other mental features than personality are regarded important. Patient anxiety is one. Anxious and nervous patients are more prone to respond to a placebo. Another important feature is positive patient expectancy. The expectancy of a patient works as a kind of self promising prophecy. If he believes in the treatment he is receiving, he is prone for a placebo effect.

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[12] Kaada, B. Nocebo-The opposite of Placebo. Tidskr. Norske Lægeforen. 1989; 109, 7-8: 814-21

Freund[13] has focused on the role of the physician. Some doctors seem to be good "placebo inducers" and some less good. A good placebo inducer communicates his own expectancy of treatment success to the patient and can be linked with high placebo effects. This process of communication is non-verbal and of a subtle and complex nature. There is a lack of quality articles on the physician's contribution to the placebo effect, and especially on the elements of the process of communication. However, Shapiro[14] claims that the self-assured and enthusiastic physician is the ideal placebo inducer. The authority and status of the doctor is important, as well as the active interest of the physician in the patient or treatment.

Out of the futile attempts to isolate definite personality features that could be linked to the placebo effect has grown the notion of "the clinical setting". The clinical setting is the dynamic situation around a clinical encounter between a doctor and a patient. Though a notoriously vague notion it emphasises the dynamic complexity of the placebo effect. It points out that not only the psychological features of an enthusiastic physician and an anxious patient are of importance for a placebo effect, but more generally the setting, the framework in which the doctor and the patients find themselves. In a classical study Beecher[15] describes how the soldiers wounded in a battle in the second world war required half as much morphine as civilians after surgery. He interprets this example of a placebo effect as closely associated with the soldier's clinical setting. Their perception of their general situation, their clinical setting, was

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13 Freund, J. et al. The doctor-patient relationship and drug effect. Clinical pharmacology and therapeutics 1972;13:172-80.
14 See note 10: p.603-5.
15 Beecher, H. Control of Suffering in Severe Trauma. JAMA 1960;173:534-6.

fundamentally different from that of normal civilian post-operative patients. Instead of the horrors of more combat, the wounded soldiers could look forward to a safe journey home. That they had escaped the horrors of war overshadowed the normal anxiety of the outcome of the operation and the unfamiliar environment of a hospital.

What is the mechanism of the placebo effect? This very important question has not yet any substantial answer. There have been some attempts to explain the placebo effect in terms of psycho-neuro-endocrinology. A study supporting psycho-neuro-endocrinology was made by Levine, Gordon and Fields[16]. They demonstrated that placebo administration is linked with increased circulating endorphine concentration. Furthermore, they showed that naloxone, an opioid antagonist, reversed the pain reduction induced by the placebo prescription. Levine's results has been criticised, for example by Skovlund[17], and is anyway nothing more than one intermediary mechanism. The opoid theory does not provide us with an explanation *why* endorphines are released, and more general how non-analgesia placebos work. Others have tried to explain the placebo effect as classical conditioning[18], Freudian transference[19] or hypnotic suggestibility[20]. None of the theories have had the explanatory power to create a theoretical consensus.

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16 Levine,JD. Gordon, NC. Fields, HL. The mechanism of placebo analgesia. Lancet 1978;2:654-57.

17 Skovlund, Eva. Tidskr. Nor. Lægeforen. 1991;111:2728-31.

18 Wickramasekera, I. A Conditioned Response Model of the Placebo Effect: Predictions from the Model. In White, L et al, eds. Placebo: Theory Research and Mechanisms. The Guilford Press. New York 1985: 255-87.

19 Forrer, GR. Psychoanalytic Theory of Placebo. Diseases in the Nervous System 1964;25:655-61.

20 Deltito, JA. Suggestibility and Placebo Effect. Clinical and Experimental Reumatology 1985;3: 97-98.

At the present moment the underlying causes of the placebo effect are badly understood. However, what most researchers today agree on is that the placebo effect has to be seen as a result of the doctor-patient relationship and the clinical setting. In an, at present, unexplainable way the clinical setting and the doctor-patient relationship are the initiators of the placebo effect.

I will end this presentation of the central features of the placebo effect by making clear some distinctions of the different types of placebos that until now I have treated as one. The distinctions will serve as a terminology that I will make use of throughout the thesis, but are presented in this section as they each illustrate different aspects of the general term "placebo". One subclass of placebo I call "*intended placebo.*" This term describes the classic situation when a doctor believes the substance he is prescribing is a placebo and deliberately gives it to a patient. Dr. Pascal's injection of salt water in the introductory section is a example of intended placebo. However, one can also speak of "*unintended placebo*". The unintended placebo is a term describing the situation when a doctor believes that the treatment he is offering has a specific effect, but where the doctor is in fact wrong. Many historical treatments have been unintended placebos, as for example blood letting. A third category of placebos are "*impure placebos.*" The term "impure placebo" describes the situation when a doctor knowingly and intendingly prescribes an active medicine, but based on a very doubtful indication. For example most sore throats or colds have a viral etiology, but very often a doctor will prescribe penicillin, only active against bacterial infections. The penicillin tablet is not an intended placebo, because it has a pharmacological effect. However,

its pharmacological effect does not influence the disease in question. The fourth type of placebo I will call *"parallel placebo"*. "Parallel placebo" is a term that aims at describing the situation where the placebo effect and the pharmacological effect work parallel. Imagine a situation where an intended placebo works, for example, on a patient with a bacterial throat infection. Without the patients knowledge the placebo tablet is exchanged with the normal treatment, penicillin. In such a case it is implausible that the previously active placebo effect would suddenly stop working at the moment the specific treatment is initiated. A more reasonable suggestion is that a placebo effect is paralleled, or complemented, by the ordinary treatment.

The history of placebos

Placebos have been prescribed for a long time, but there are few historical references to placebos, and it is difficult to get an impression of how frequently they were used. Still there is something to be said for the view that placebo prescriptions were not altogether rare. Thomas Jefferson writes to a friend in 1807:

" One of the most successful physicians I have ever known, has ensured me, that he used more bread pills, drops of coloured water, & powders of hickory ashes, than of all other medicine put together.[21]

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21 Blanton, WB, Medicine in Virginia in the eighteenth century. Garret and Massie. Richmond 1931: p.198-199.

A different aspect of the history of placebo is the prescription of the unintended placebo. Medical history is full of illustrative examples, but maybe "the King's disease" (scrofula) is one of the most spectacular. The cure for this form of TB was the touch of the king's hand, called "the royal touch". It is believed that Charles the Second treated nearly a hundred thousand patients in his lifetime. Shapiro[26] describes enthusiastically the whole pre-scientific history of medicine as the history of placebos. I assume he means the history of unintended placebos, but his rather strong claim does not take into account other factors than the treatment itself influencing the recovery from a disease. Natural remission is but one example. Still, the relative success of many obsolete therapies suggest that the placebo effect was a crucial element of many historical therapeutical procedures.

Intended placebos have been part of medical praxis for centuries, unintended placebos probably since early days of mankind. However, placebos have not played any role in medical research before the middle of this century. Placebos got a fundamentally new role as a result of the pharmacological revolution after the Second World War. It became linked with what is known as the "Critical Clinical School" of medicine. The Critical Clinical School focuses on assessing efficiency of different therapies, and use controlled trials and statistical methods for that end. Before I will discuss the importance of placebos in what today is the paradigmatic method of clinical research I will trace the historical roots of the Critical Clinical School.

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[26] See note 3: p.114.

The French medical historian and philosopher Michel Foucault[27] discusses in his book "The Birth of the Clinic" when clinical science was "born". He argues that a turning point was reached in 1801 with the publication of what can be regarded as one of the most important books in the history of medicine: "Anatomie Générale", written by the Frenchman Xavier Bichat. The remarkable achievement of Bichat was that the scientific knowledge of anatomy became linked to the clinical practice, resulting in the field of pathological anatomy. As expressed by Michel Foucault the "clinical gaze"[28] was introduced. In the next half century a major interest in the clinical aspect of medicine followed. The stethoscope was introduced and the entire system of diseases were renamed within the pathological framework. In the 1840 J. Gavaret then published "Principes généraux de statestique médicale". A book focusing on the application of statistical methods in evaluation of clinical practice. Gavaret describes in principle the procedures, that not before the last decades have changed clinical science. He speaks of the necessity of a control group, and discusses the problems regarding patient allocation and the statistical and structural biases in the assessment of a therapy. This type of clinical investigation soon produced practical results. During the 19th century most of the old panaceas, such as unicorn horn, were subjected to the new methodological acid bath and were all judged worthless. This depressing result was part of the background promoting the trend in 19th century medicine known as "therapeutical nihilism". The

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27 Foucault, M. The Birth of the Clinic: An Archeology of Medical Perception. Vintage Books. New York 1975.
28 Ibid.

acid bath was so strong that it destroyed its container. Most doctors turned their scientific interest away from the clinic and entered the laboratory. Claude Bernard was an important pioneer in experimental physiology. Bacteriology and anaesthesiology as well, soon proved their worth, and Gavaret´s exact "numerical method" was forgotten for almost 100 years.

Placebo and the modern controlled clinical trial

Vast numbers of therapeutically active, but also potentially harmful drugs have been introduced since the pharmacological revolution of the fifties. Penicillin and the other antibiotics have radically changed the treatment of infectious diseases but, for example, the thalidomide catastrophe illustrates in a morbid way the danger of not methodologically thoroughly testing the effects of a drug. Britain pioneered the field of clinical trials that now dominates clinical research. In 1931 the Therapeutics trial committee was formed by the Medical research Council and in 1948 the same council implemented its study on streptomycin treatment of tuberculosis. The streptomycin trial was the first major clinical trial using the methodology of placebo controls. Since then almost every clinical trial with some credibility has a design were the placebo effect is an integrated part. It is no exaggeration to say that the placebo effect today is of massive importance to clinical research methodology.

The important streptomycin study from '48 shows the basic characteristics of a modern clinical trial. The idea behind a clinical

trial is to select a representative group of patients and divide them in two in principle identical groups. One group will receive a treatment and the other a placebo. The difference in therapeutical outcome is assessed statistically. If the difference is accepted as statistically significant, the treatment is regarded as the cause for the therapeutical effect. The result of the trial is then extrapolated to clinical practice. To enable any reasonable correlation between cause and effect, and any valid extrapolation from the small selected group of patients to the general population, an impressive number of potential biases must be thwarted. One important bias is selection bias. The ideal situation to have two identical groups of patients is not possible, so to minimise any important difference between the two groups it is paramount to randomly allocate patients to the two groups. There has to be a defined inclusion or exclusion criteria for the patients that are going to be part of the trial and any kind of active selection has to be avoided. Furthermore there are many structural problems and possible biases that have to do with the statistical analysis of the results of the trial.

The type of structural bias that is most relevant for the placebo effect has to do with the "double blinded design". The patients and the implicated doctors of a modern trial are "blinded" so that they have no knowledge of who is in the control group, or as it is often called "the placebo group"- and who receives the potential active treatment. The major reason for this new feature of clinical trial is an attempt to prevent a certain type of bias. There are two important sources of structural biases concerning the blinding procedure. One has to do with observer bias. The examination of a

physician who knows that the patient he is examining is in the control group is often more superficial. The doctor's expectation that nothing is going to happen to a patient might prevent the physician from observing important signs, and as well communicate non-verbaly to the patient the fact that he is not receiving active treatment. The second source of bias is the placebo effect. It is estimated that patients believing they are in the treatment group will be more prone to a placebo effect than those who are certain they are receiving sugar pills. There are many examples of modern uncontrolled, or single blinded trials that have erroneously concluded that a tested treatment was specific. A famous example of the importance of placebo bias is described by Beecher[29]. In the fifties before the introduction of new operations demanded a double blind trial, a promising surgical procedure for treating angina was advocated. It consisted in the ligation of the inner mammary artery, and the idea behind the operation was to increase the collateral cardiac blood flow through a local increase in blood pressure. The results were regarded positive. Three years later, after a considerable number of operations, a double blind trial was carried out that showed that an exposure of the artery without the ligation gave the same effects. The operational procedure was immediately stopped. Beecher interprets the trial as an evidence of a strong surgical placebo effect.[30]

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[29] Beecher, HK. Surgery as Placebo. JAMA 1961;176(13):88-92.

[30] There is no attempt in Beechers analysis to assess how much of the "effect" was placebo effect and what has to be ascribed to observer bias. However, I assume that at least a considerable part of the reported therapeutical success is a placebo effect.

Chapter two:

Defining "Placebo effect"

Definitions are one of the corner stones of any scientific or academic pursuit. In the attempt to analyse a complex and veiled subject matter the process of defining and redefining becomes paramount. In this aspect the research on placebo differs little from other scientific projects. Much attention has been focused on a formal definition of placebo. However, the reasonable degree of consensus usually existing within a scientific community framing a definition,

seems not present with regard to the placebo effect. Brody[31] discusses pros and cons of restrictive and broad definitions. Pepper[32] represents the restrictive end of the scale since he sees placebo as totally inert, whereas Modell[33] represents the other extreme position when he states that the placebo effect is "the only single action which all drugs have in common". One of the most respected researchers in the field, Shapiro[34], bases his definition on the notion of specificity. Placebo has an "unspecific" effect whereas pharmacological treatment is supposedly "specific". Grunbaum[35] criticises this terminology, and suggests his own, based on the difference between what he calls "characteristic" and "incidental" treatment factors. I will discuss their terminology later, and at present restrict myself to note the difficulty many researchers have had in defining placebo. At the moment there exists no general accepted definition of the much used medical term: "the placebo effect".

Real and nominal definitions

A concern with definitions can be traced back to Aristotle. He describes the act of defining in his "Topics" as:

"a phrase signifying a thing's essence"[36].

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31 See note 6: p.9.

32 Pepper, O. A note on placebos. American Journal of Pharmacy 1945;117:409-12.

33 Modell, W. The relief of symptoms. Saunders and Co. Philadelfia 1955: p.55.

34 See note 10: p.599.

35 Grunbaum, A. The placebo concept in medicine and psychiatry. Psychological Medicine 1986;16:19-38

36 Aristotle. Topics, 100a-102b26

However, in his "Posterior Analytics" he also describes a definition as:

"... a "thesis" or "laying something down", since the arithmetician lays it down that to be a unit is to be quantitatively indivisible; but it is not a hypothesis, for to define what a unit is is not the same as to affirm its existence."[37]

The logical tradition evolving from his works distinguishes between the two different approaches: the "laying down", and "formulating the essence" as respectively *"nominal definitions"* and *"real definitions"* . The former tries to grasp the essence of an entity, and is based on the ontological assumption that the world around us is real and not imaginary, and that it consists of entities which have describeable properties, that distinguish them from other entities. A real definition crystalises the distinguishing properties for the phenomenon in question. Sometimes it is formulated scholasticly as a definition "per genus proximum et differentiam specificam". Here the phenomenon to be defined is categorised as a species relating to a special class or genus. Today many philosophers are uneasy about the term, and want to restrict the notion of a definition to a nominal definition. Many phenomena are undefinable as real definitions, but still *real* like love, angst or even health[38]. Some definitions can not be rushed to before a scrutiny, and are the results, not the initiators of an analysis, for example the redefinition of a gene as DNA. Often

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37 Aristotle. Posterior Analytics, 71a1-72b25

38 On the definitorical problems of "health" see e.g. Boorse, C. Health as a Theoretical Concept. Philosophy of science 1977;44:542-73, or Kraupl-Taylor, F. The Concepts of Illness, Disease and Morbus. Cambridge University Press. Cambridge 1979.

the intention of the real definition: to get a precise description of an entity, is better taken care of by a scientific or philosophical analysis.

The real definition is historically linked with the classification endeavours of the 18th century. The well-known botanical system of Linné[39], and also his less known nosological classification, are typical of a scientific approach that presupposes nature as so complying that grasping its real essence is a question of defining more than analysing. The French nosologist Francois de Sauvages introduced a classification system in medicine with his "Methodica sistens morborum classes, genera et species" from 1763. He divides asthma into 19 species and angina into 18. The idea of a critical, and often empirically guided, analysis of "the real" in clinical medicine was not implemented before the pathological anatomical revolution circa 1800. However, even today one can detect certain tendencies in medical terminology that indicate the historical heritage from Sauvages. Most textbooks in medicine "define" a disease in the beginning of each chapter. But when one reads the so called definition it becomes clear that it is really an ultra-short description[40]. The tendency to regard definitions as real definitions is still a part of modern medicine.

A nominal definition, on the contrary, does not involve making the ontological claim of having arrived at an essential or complete description of an entity. Rather it accepts the common experience

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39 Linné, C. Systema Natura, and Genera Morborum. Quoted in Faber, K. Nosography. P. B. Hoeber. New York 1930: p. 22.
40 Wulff, HR. Rationel Klinik. Munksgaard. København 1981:p. 75.

that we often hold different meanings for the same word, and that we often claim to know "essentials" about the "real", that we later find to be erroneous. Nominal definitions do not claim to say anything *certain* about the "real world", but are useful heuristic tools in the continuous wrestling game with obstinate entities like "truth" and "reality". Some nominal definitions are tautologies, but their usefulness would be minimal if they were not related to "the real" in some sense: if they were only word-word relations and not word-thing reflections. The important difference, though, is that they do not claim to *be* the essence. They are a linguistic apparatus in the construction of what we regard as the essence. Wittgenstein[41] argues in his "Philosophical Investigations" against the belief that everything can be defined. He exemplifies this by demonstrating the impossibility of defining even well-known entities like a "chair" or a "leaf". This could be seen as a general jettison of definitions. However, a more constructive interpretation is to regard it as an rejection of real definitions. If I were to define "placamba" as the placebo effect caused by dancing samba with your doctor, this definition would be logically possible, and the term can be used, though of course in a practical sense it is hopelessly useless. Euclideus´ definition of a line as a length without a breadth has had immense influence, but would be impossible to defend as a real definition. It is simply something that never has been seen in the real world. A nominal definition, however, does not make that claim, and can be regarded as a tentative attempt to make explicit, sharpen or even reconstruct the rules of a specific "language game".

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41 Witgenstein, L. Philosophical Investigations. Basil Blackwell. Oxford 1958: pp. 32e-39e.

One variant of the nominal definition is the *"ostensive"* definition. That is giving an example. Explaining a colour is often done with reference to an object having that colour. In the introduction I described a clinical situation that exemplified the placebo. In other words I gave an ostensive definition of the phenomenon. Another type of nominal definition is the *"lexical"* definition. It is the reportive description of how a term is actually used. The definition or short description in a dictionary is the typical example. The different dictionary quotations I gave in the historical section were lexical definitions of placebo. A third variant of the nominal definition is called *"stipulative"*. It is what authors often aim at when attempting "conceptual clarification". A stipulative definition selects one preferred meaning of the word with the object to remove ambiguity. It often explains why this meaning is preferable to a certain purpose, and also often tries to explain former disagreements as "terminological misunderstandings". The placebo definitions offered for example by Grunbaum[42] have certain features in common with the stipulative definition.

Two definitions of placebo

In the following I have shortened, but not in any important way changed, the definition of "placebo" that Shapiro[43] offers in his article "The placebo response":

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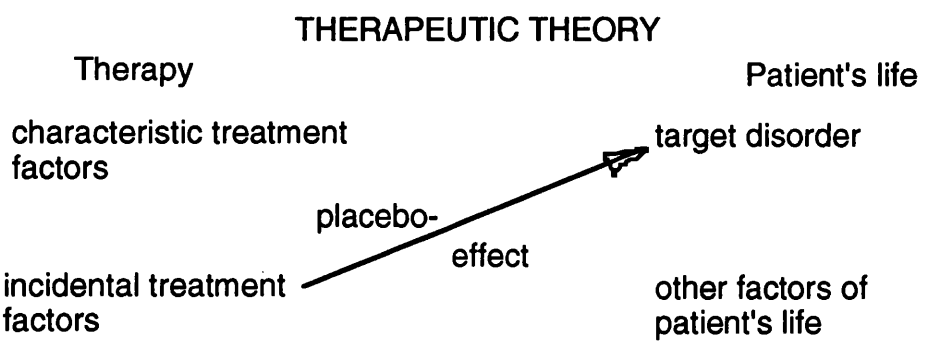
[42] See note 35
[43] See note 10

A placebo is any therapy that is deliberately used for its nonspecific psychological effects, or that is used for its presumed effect, but which, unknown to patient and doctor, has no specific effect.

Shapiro's approach does not include a consideration of the potential inclusions or exclusions following from his definition. Though he claims that his definition provides "a good model for research" I think his definition runs into fundamental problems. What Shapiro here is offering is an ultra short description of placebos. His "definition" is analogous to how a textbook of medicine would describe, or "define" a disease entity, and is in fact a real definition. In a practical context this may matter little if the definition did not contain ambiguity. However, the central clarifying notions of "specific" and "nonspecific" are not elaborated and are concepts that are notoriously ambiguous.

Grunbaum's article "The placebo concept in medicine and psychiatry" criticises Shapiro's' use of ambiguous terms like "specific" and "unspecific", and offers his own alternative definition. Grunbaum builds his definition on the following model:



In the left hand side of the figure above, the "characteristic treatment factors" are the therapeutical procedures a clinical theory will point out as the treatment. They are the factors that constitute the intentional treatment, for example penicillin within present microbiological theory. However, other factors can be of clinical importance to a therapy, factors Grunbaum calls "incidental". The water a patient drinks to swallow his penicillin is an example of an incidental treatment factor. In the right hand side a "target disorder" is the disease that the therapeutic theory predicts as being effected by the characteristic treatment factors. Bacterial Tonsillitis is one example. Side effects are characteristic treatment factors that affects "other factors of patient's life". Placebo is defined as an "incidental treatment factor" affecting a "target disorder".

Grunbaum's definition has the advantage that it more clearly than Shapiro's points out the importance of the therapeutical background theory for the categorisation of a therapy as a placebo. Furthermore his definition is based on detailed considerations of the consequences of his definition on medicine and especially on psychiatry. Regardless of other points of criticism one cannot claim that Grunbaum offers a real definition. His definition is a stipulative nominal definition. However, despite the formal character of Grunbaum's definition there still are objections to be made about his definition.

A consequence of his definition is that the structure of the therapeutical theory constitutes what is an incidental treatment factor. Thus one can have two alternative theories constituting the same therapeutical procedure as belonging to two incongruous categories. One theory considers a therapy as incidental and the other theory might consider the same therapy as characteristic. What is a placebo in one theory is not a placebo in another. The historical evolution of placebo therapy tends to support his definition. The historical reinterpretation of therapies like blood letting, once believed to have specific properties, now believed to be a placebo, is at least partly a result of change in therapeutical theory. However, seen with contemporary eyes the strict conceptual link between the placebo notion and the background theory is problematic because it does not incorporate an empirical dimension into the placebo definition. The discussion whether a therapy is a placebo or not, reaches back to which of several theories one prefers, thereby constituting a therapy as either placebo or non-placebo. There is no indication in his paper of what makes one theory preferable to the other. From an empirical position this is unsatisfactory.

A paradox follows his line of arguments. Suppose one gives placebo a status as a therapy proven effective in for example chronic pain treatment (migraine), and with the limitations of its use, parallel to the limitation of indication area of every treatment, integrate it in the pain treatment apparatus. This could happen, as pain perception is one of the areas were the placebo effect is documented the best. Many other therapies that work are unexplainable at the moment, for example shock therapy for

depressive psychosis. This incorporation of placebo in the therapeutical arsenal would mean placebo changed status from an incidental to a characteristic treatment factor, and thus the therapy known as placebo would at the same time not be a placebo.

A possible explanation why Grunbaum so radically avoids the empirical dimension in his definition is that one of his intentions is to distinguish psychotherapy from the placebo effect. It is worth noting that there exists a general disagreement about the specificity and effectivity of psychotherapy. Some see it as specific, others as unspecific, and others again as an therapeutical illusion. Grunbaum wants to distinguish sharply between psychotherapy and placebo effect, thereby immunising psychotherapy from the critique that it is nothing more than placebo. In a conceptual way Grunbaum does that. It is a consequence of his definition that the theory behind psychotherapy points out characteristic treatment factors, for example that a therapist should interpret the patient's free associations in special ways; any therapeutical effect not explained by the psycho-analytical theory is based on incidental treatment factors. The incidental treatment factors having effect on the target disorder are placebos. The empirical problem not addressed by Grunbaum is whether psychotherapy as such has an effect.

I must conclude that though Grunbaum intends a stipulative definition, and correctly points out weak points in Shapiro's definition his alternative is problematic as well. In a semantic way he "saves" psychoanalysis from the critics saying it is nothing but placebo, but he does not clarify the terminology for either medicine or psychiatry in general. His suggestion, though possible as a formal

procedure, similar to defining "placamba", is not clarifying for the praxis of understanding, researching and using placebos. It is a word-word definition, not a word-thing definition.

The empirical substantiation of the placebo effect

To be able to make a useful word-thing definition one has at least to have a good idea of what this "thing" is. The most elaborated definition cannot hide the fact that "defining" an entity whose nature is not properly documented is like searching for one's glasses blind-folded. All working on the placebo effect agree that more research is necessary, and that we know fairly little about the central mechanisms of the placebo effect. This lack of knowledge of the causal relations leading to a placebo effect is less important because it is integrated in most placebo definitions, for example both Shapiro's and Grunbaum's. However, there is little mistrust in the empirical material documenting the size and structure of the placebo response. Most researchers in the field of placebo regard the placebo effect as well documented. My review of the features of the placebo effect in the previous chapter is an intended loyal account of the general accepted position. The problem is that many of the articles referred to as documentation for the features of the placebo effect have methodological flaws. My assertion is that the empirical material on which definition and a philosophical analysis should rest is not as certain as many would hope. To substantiate this claim in any reasonable degree of detail would extend the scope of this work, but I will in the following illustrate that it is not taken out of the blue.

Before I point out the most eye-catching methodological problems of the placebo articles, I think it would be useful to distinguish between two periods of research on placebo, and therefore between two generations of articles. One class of articles are "the classical" articles. They are written from Pepper's[44] first ever published article on placebo in 1948 to the mid-sixties where the placebo effect become increasingly conceptualised as a research bias. The period following thereafter showed a decline in the interest in the placebo effect, a decline that not until recently has been challenged. A problem shared by both the modern and the classical articles is that there exists no trial that is designed especially to measure the placebo effect. Double blind trails are designed to measure a pharmacological or surgical effect and for that end they subtract all other therapeutical factors as bias, including the placebo effect. Any conclusion of the nature and size of the placebo effect on that basis runs the risk of being distorted. The major problem is that what are regarded as placebo effects in clinical trials often cover many different therapeutical factors. The most important non-placebo and non-pharmacological factor is the natural remission. Most patients get well without the interference of a doctor or a therapy. This self-healing capacity of the body most not be included in a meaningful placebo quantification. However, in articles reporting high placebo rates there is very rarely even a discussion about the distinction between the placebo effect and the natural remission. One popular myth is that the placebo effect for analgesia for headache reaches 80 %. Possibly this myth can be traced back to an

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[44] See note 32

article by Jelinek[45] who found that 79 out of 120 patients with headache got considerably better on placebo. The problem not addressed in this, and many more studies, is that most patients get better anyway. A headache normally only lasts for a few hours. It corresponds to saying that the placebo effect in common colds is 100 % after three weeks, as practically all common colds maximally lasts for a few weeks. What is needed for a sound substantiation of the placebo effect is a trial design focusing on the placebo and integrating the other therapeutic factors as biases. I will in one of the following chapters discus the possibility of such a trial design.

A problem primarily regarding the classical articles is that not only do their design focus on the pharmacological effect of a treatment, but seen with contemporary critical eyes, that design in itself contains several methodological flaws, making them even more unsuited for conclusive evidence. This would not matter very much if they only had historical importance, but actually many of the classical articles are quoted repeatedly as substantiation in contemporary papers. One of the most important classical articles is written by Beecher[46] in 1955: "The powerful placebo". It is a meta-analysis of fifteen trials with the aim of substantiating the effectivity and range of the placebo effect. A considerable proportion of contemporary articles quote Beecher for two radical conclusions. One is that the placebo effect produces "satisfactorial relief" in about 35 % of patients. The second is that placebo generally affects all kinds of symptoms and diseases. Are the conclusions defensible if one scrutinizes the article? Beecher's

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[45] Jalinek, 1946, quoted in note 46.
[46] Beecher, HK. The Powerful Placebo. JAMA 1955;159(17):1602-6

method consists in pooling both the conditions and the patients used in the different trials into 9 categories: post-operative pain, cough, drug-induced mood changes, angina pectoris pain, headache, seasickness, anxiety, experimental cough and common cold. He notes the placebo effect in each trial and calculates the mean. However impressive it may be to refer to the 1082 patients partitioning, his approach would not be accepted to day. A good meta-analysis must distinguish and intend to counter certain possible biases, that are left uncommented in Beecher's article, for example, "combinabillity". Sacks[47] writes:*"A major issue in pooling data is whether the results of the separate trials can be meaningfully combined."* In Beecher's article there is no discussion whether the different trials he is pooling have similar inclusion/exclusion criteria, furthermore there is no operational definition of the diagnostic criteria for the used therapeutical units, what constitutes for example the difference between the two used units "cough" and "common cold"?

The second major problem with the article is its applicability. There is no discussion about the validity of the range of the article's conclusion. Possibly the placebo effect has an significant influence on the used diagnostic units, but that does not imply that the placebo effect affects all other diseases and ailments. The recorded placebo effects in pain, cough and seasickness is 35 %. That placebo is effective in certain conditions where pain is a strong component would be a more prudent conclusion. However, the article is used to

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[47] Sacks, HS. et al. Meta-analyses of Randomized Controlled Trials. The New England Journal of Medicine 1987;316(8):451

substantiate that the placebo effect is generally 35 %, thus including placebo responses in conditions like cancer or AMI.

Spiro[48] in his critical review of the material regarding the placebo effect concludes that placebo has no effect on illness but only on disease. That is to say it modulates symptoms, but has no effect on the underlying pathological processes. I think his conclusion is too square cut, and based on a too simple distinction between symptoms and disease. However, it is but one example that there is a general lack of consensus about even such a fundamental question. My intention here is not to answer the questions, but to point out that the uncertainty is not restricted to the causal nature of the placebo effect, but also to the substantiation of its range and size, carrying implication for a philosophical analysis of the notion. Firstly, it does not necessarily effect a philosophical approach whether the placebo effect is 15% or 75% effective in a given disease (of course this is of paramount clinical importance), but it does make a substantial difference if central qualitative features are to be questioned, thus transposing the problem from a theoretical medical to a philosophical discussion. If placebo for example is only symptomatically effective, as Spiro claims, what are the implications to for example medical ethics or the mind-body problem? Secondly, a useful word-thing definition of the placebo effect is difficult to make if both the causal mechanisms are unknown and the empirical substantiation of the size and range of the effect is uncertain. An important aspect of the problems of defining the placebo effect has to do with the fact that the

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[48] See note 25: p.75-97.

knowledge on which a formal definition should rest is not as rock-bottom as one might wish.

A cartographic definition

Instead of making another stipulative definition, a more useful definition is one that could be called a "cartographic" definition. A cartographic definition is a detailed lexical definition focusing on the different ways the term "placebo" and "placebo effect" is used in the literature, but distinguishes itself from a lexical definition by including a focus on which sense of the term I intend to use in this work. The following takes the form of a guide to the way the notion "placebo" and "placebo effect" is actually used in the literature, supplemented by my concluding working definition.

One of the most striking features of the general medical approach to the placebo effect is the disharmony between the vast use of the term and the lack of research focusing on it. In most textbooks on medicine there are no references to the placebo effect. This includes Kumar and Clark´s[49] describing itself as "the most used textbook on clinical medicine in the UK". Some textbooks on pharmacology[50] have a section on placebos, but mostly strictly viewed as a research bias. Even Wulff´s[51] in other aspects impressive book on medical methodology treats the placebo notion

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[49] Textbook of Clinical Medicine. Ed. Kumar, PS & Clark, ML. Bailliere Tindall. London 1990

[50] Lewis´s Pharmacology, 5th. ed. Churchill Livingstone. Edinburgh 1980: p.144-145.

[51] See note 40: p. 206-209.

stepmotherly. This contrasts the immense use of the term in research articles. Alone in 1992 there were internationally published about 1500 articles where placebo appears in the abstract[52]. The vast majority had titles of the following character: A placebo controlled trail of the effect of drug X on disease Y. A small minority were concerned about the phenomenon itself, and consisted of editorials, letters to the editor, clinical studies and a few review articles.

Firstly I will focus on the use of the term that expresses common logical errors. Some commentators see placebo as a purely linguistic construction. Usually they put inverted commas on the noun: "effect", and treat the phenomenon as a reminiscence from a pre-scientific period. In an illogical way they do not see the clinical effect as real, as it is not explicable in biological terms. This attitude is paradoxically often paired with the emphasis on placebo as an irritating, but real, research bias. One could call this "the fallacy of the effect in inverted commas". Many authors express it implicitly[53]. A good example, however, of an explicit fallacy is in a letter to the editor of the JAMA, where Gaudet[54], in a discussion about placebo in migraine trials, uses the phrase *"the true effect of a medication"*, relating it to the total effect minus the placebo effect. A more frequent and systematic problematic use of the term is related to the terminology of the double blind trial. One variant of names given to the modern trials is placebo controlled trials. Most

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52 Search on the MEDLINE search system for the year 1992. Searchword: "placebo", Limitation: "abstracts".

53 Dicket, LG & Rees, TS. Placebo Effect in Tinnitus Management. Otolaryngology-Head and Neck Surgery 1984;92(6):696-9.

54 Gaudet, RJ. Migraine Prevention with ß-blockers: A Placebo effect? JAMA 1985;254(22):3183-4.

of the articles call the control group the *placebo group,* and the pharmacological inert tablet the *placebo-tablet.* This is conceptually unsatisfying because the phrase "placebo-group" disguises the fact that other factors than placebo are involved in the improvement of the control group, and furthermore because a placebo effect is present in the treatment group as well. Some investigators use an unctuous vocabulary when praising their research object and refer to placebo effects close to 100 %. Couch and Dobrilla[55] rapport placebo effects in ventricular ulcers and in chronic headache that are as high as 60-80 %. However, as I have pointed out in the previous heading, the quantification of the placebo effect is highly uncertain. Many articles include in the placebo effect what must be attributed to natural healing processes, or what sometimes is called "spontaneous remission". This is even more important when dealing with a disease with cyclic symptoms as ventricular ulcer or chronic headache. There is as well a tendency to regard the*"placebo-tablet"* as having a mystical power of a pseudo-pharmacological character, as if the tablet was *the cause* of the placebo effect. The tablet probably has some effect, as trials show a difference in the placebo effect that for example can be attributed to the colour and size of the tablet. But its importance is only as a part of the general clinical setting. The importance of the pill or any other placebo procedure or prescription is of a symbolic nature.

Now I will turn to the use of the placebo notion that differs in the interpretation of the clinical data on the phenomenon.

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[55] Couch Jr, JR. Placebo Effect and Clinical Trails in Migraine Therapy. Neuroepidemiology 1987;6:178-85, and:
Dobrilla, G. Placebo in Evaluation of Antiulcer Drugs. Int. J. Tiss. Reac 1983; V(4):329-337

Possibly the most common view among physicians is that placebo has no effect on the illness itself, but "only" affects the symptoms. Spiro[56] and Skrabanek[57] represent this view. Brody regards placebos as having effects both on symptoms and on illness but with different efficiency on different conditions. Pain perception is more effected by a placebo than for example an infection, and even less so a malign cancer. A last position regard placebo as a panaceas. A kind of wonder cure with no limits to its ability: it causes death, heals the lame and make the blind see. Lasagne[58] and Shapiro[59] are close to this view.

Within the practical clinical context the placebo effect is generally accepted as a phenomenon, but the attitudes towards it can be divided into three standard positions. The "softliners" regard the placebo effect as a therapeutic tool, maybe not in line with pharmacological active drugs, but one procedure of many that at least sometimes work. In special circumstances it is ethical and scientifically defendable to use. The "hardliners" regard the use of placebos as a residue from a pre-scientific period and unprofessional, as the effect is regarded as unspecific, only related to symptoms, or even a therapeutical illusion. The use of placebos is also seen as unethical because it involves deceiving your patients. A third group, possibly the biggest, prescribe impure placebos, often antibiotics or vitamins on pseudo-indications. They want to make

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56 See note 25: p.75-97.

57 Skrabanek, P & McCormick. Follies and Fallacies in Medicine. The Tarragon Press. Glasgow 1989: p.6

58 See note 4:161-3.

59 See note 10

use of the potential therapeutic effect, but recognise the criticism of the hardliners.

As a concluding paragraph I will summarise the discussions above. I regard "the placebo effect" as the therapeutical effect caused by the patient's interpretation of the clinical setting and the psychological interaction with the physician. I regard the effect as most dominant in pain conditions. Other symptoms and diseases are in a various degree affected. I regard "the placebo" as the procedure the physician presents as the apparent therapy, but which is surgically and pharmacologically inert. The placebo serves as a token symbol having an important, but not necessary, role in the initiation of the placebo effect. However, the placebo effect can, in certain situations, be initiated without such a specific token, solely as a result of the doctor-patient relation. It is important to separate the placebo as a token from the placebo effect. The causal background of the placebo effect is a multifactorial complex often including a token placebo, but important to recognise in itself. The causal mechanisms initiating the placebo effect, the clinical setting and the doctor-patient relationship, are better described in the term "the placebogenic complex." The placebo is thus one of many factors in the placebogenic complex. In chapter six I will in more detail discuss the notion of placebogenic complex. The rest of the thesis will emphasise the notion of placebo effect compared to the placebo.

Chapter three:

The scientific medical model

Models and paradigms

In theory of medicine, discussions of different "models" of medicine are predominant. In many textbooks on social medicine, philosophy of medicine or psychiatry, different medical models are discussed and elaborated. A general trend in these discussions of models is a critique and refutation of the "bio-medical" model, and a promotion of a broader "bio-psycho-social model". The Bio-medical model is normally conceived to be the present dominant scientific and technical way of practicing medicine. The Bio-psycho-social model is regarded as an alternative that incorporates psychological and social explanations of disease. Other medical models have been formulated. Medical anthropologists talk about the "mythico-religious medical model" and in social medicine the "folk medicine model" have attracted interest. The different medical models contrast with each other in many ways, but it is important to emphasise that they all have one thing in common. They represent concepts and routines that enable individuals in a specific community to "understand" and cope with disease. In that sense there is no difference between the interpretation of a headache as either a intrusion of an evil spirit or as migraine. Both interpretations provide concepts that explain the pain, and provide a framework for a possible (and often ineffective) therapy.

In most articles on medical models, there is little elaboration of what is actually meant by the central term "model". This lack of

conceptual clarification is unsatisfactory. When the purpose of an article is to criticise what is called the Bio-medical model it is important to make explicit what is more precisely meant by such a model and to reflect whether that model roughly corresponds to our intuitions about the content of contemporary medicine. A superficial account of the concept of a "model" induces the risk of aiming one's arguments at a straw man instead of focusing on the real weakness and strength of modern medicine. An alternatively sound way of avoiding a theoretical discussion on "model" is to refer to a previous elaboration. The works of Thomas Kuhn[60] comes to mind. Hahn[61] discusses the placebo effect as an example of a deviant phenomenon within the bio-medical model. In his article "A Sociocultural Model of Illness and healing" he writes: *"I contend that ... the placebo phenomena represents a profound anomaly to the paradigm of Bio-medicine."* Hahn's approach is typical in the sense that he does not develop his central term of a model; however, he does use a Kuhnian terminology when he speaks of "anomalies" and "paradigms", thus implying that his conception of a "model" corresponds to the Kuhnian "paradigm". The lack of elaboration of "model" would not matter very much if Kuhn's theory of science automatically could be transformed to the area of medicine. However, there are certain features in medicine and in Kuhn's theory that makes such a transference problematic. Before I continue with an presentation of what I mean by the "Scientific

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60 Kuhn, TS. The Structure of Scientific Revolutions (2.ed.) The University of Chicago Press. Chicago 1970

61 Hahn, RA. A Sociocultural Model of Illness and Healing. In White, L (Ed.) "Placebo-Theory, Research and Mechanisms". The Guilford Press. New York and London 1985: p. 167-95.

medical model", I will discus the applicability of a Kuhnian paradigm in medicine.

With the publication of "The structure of Scientific Revolutions" Kuhn opposes the conception shared by both the logical positivists and Popper that science develops in an evolutionary manner. On the basis of studies in history of science Kuhn emphasises the revolutionary aspect of scientific development. He describes science as consisting of two fundamentally different phases. One he calls "normal science" and the other "extraordinary science". Normal science is more or less a cumulative process. A leading metaphor in "The Structure of Scientific Revolutions" is the jigsaw puzzle. Scientists solve the "puzzles" of science. What a scientists and jigsaw puzzle solvers have in common is that neither question why the puzzle has the form it has. Kuhn says that the shared tacit assumptions and routines that are the tools of scientists, their conceptual framework, constitute a scientific paradigm. Under the guiding lines of the "paradigm" grounding the specific period of normal science, the working scientist solves the different "puzzles" that the paradigm presents. Scientists do not question the basic assumptions that his research is built on. If he tried to do that he would come nowhere and would not be able to produce any results. By concentrating on the problems within the framework or paradigm of his time a scientist will be able to solve the questions the paradigm focuses on. Slowly empirical facts will accumulate that are in contrast to the theoretical assumptions of the paradigm. Either such "anomalies" are regarded as not important or they are regarded as observations that are not certain enough. The initial response to an anomaly is to try to deny its importance. However, if

the anomaly is fundamental enough to the paradigm, and if other anomalies have accumulated as well, they become part of a scientific crises. If the old paradigm cannot handle that crisis a scientific revolution will occur where a new paradigm with a greater ability to explain both the old phenomena and the anomalies is developed. After a short period of turmoil, where the fundamental assumptions of the area in question are discussed, the new paradigm is established. Normal science is at work again, but under a new paradigm.

Kuhn's concept of paradigm have become known in much wider circles than most concepts from theory of knowledge. In the postscript to the second edition he, sour-sweetly, writes that the term *"has a life of its own"* [62], implying that frequently "paradigm" is used isolated from its theoretical context and sometimes is diluted to mean little more than a change of perspective. Though Hahn's use of the term is more sophisticated there still are three problems that make me oppose Hahn's use of the concept "paradigm" in a medical context. One is based on the analysis of Margret Mastermann[63]. She demonstrates that Kuhn uses the concept in twenty two different ways. In the postscript to the second edition Kuhn acknowledges this, but points out that many of the supposedly different forms are semantic variations. However, one fundamental difficulty with the term is that there is no attempt to distinguish different forms of paradigms. At least in medicine there is a huge difference between paradigm as scientific world

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62 See note 60: p. 187.

63 Mastermann, M. The Nature of a Paradigm in "Criticism and the Growth of knowledge" edited by Lakatos, I & Musgrave, A. Cambridge 1970.

view and paradigm as a specific research program within a emerging sub-discipline of for example bio-chemistry. The second problem touches on the range of the field of medicine. As the title of Kuhn's work indicates, he is interested in the structure of scientific development. Medicine is, however, not only a pure science as it has a much broader field than, for example, physics. In the following paragraph the range and structure of the field of medicine will be discussed in more detail. At the moment it is sufficient to refer to Kuhn's own emphasis that medicine is one area that possibly has a different status of autonomy with regard to society in general, and might be ruled by other forces than the ones he describes[64]. A third problem is the lack of coherence between the many different medical sub-disciplines. Does social medicine and clinical physiology share a medical paradigm? One possible response is that medicine consists of many different closely related paradigms, sharing what Wittgenstein call "family resemblance". However, this leads back to Mastermann's critique of Kuhn, because it emphasises the lack of systematic distinction between different sub-paradigms and more fundamental paradigms. Though the concept of a model is inspired and in many way similar to a paradigm, I think it is useful not to regard them as identical. Hahn's use of a Kuhnian terminology does not imply that a conceptual clarification of "medical model" can be omitted.

The Scientific Model of medicine

64 See note 60: p.165.

There are surprisingly few analyses, not only of what a medical model is generally, but also of what constitutes the specific "Bio-medical" model[65]. However, for example the textbook on social medicine used at the University of Copenhagen focuses on a central analogy: the error-in-the-machine-analogy[66]. A human being is regarded as a machine, a highly complex biological machine. Some times an error develops in the machine and people get sick. The errors are related to organs or cells in the complex machine, and the logical therapy is to change the biological parameters that have caused the errors. Organs are transplanted or medicine that change the function of special cells is prescribed. The relevant causes of the error in the machine are to be found in the intrinsic complexity of the machine, almost like the error of a clock hanging on the wall is due to bad construction or wear, not to an interaction with the surroundings. Though persuasive in its characterising of a narrow causality conception in medicine the analogy, like most analogies, runs the risk of being too simple.

The contemporary dominant medical model has been called the "Bio-medical model". However, I prefer to call it the "Scientific medical model". Why do I bother renaming a phrase that is close to be an established terminology? If nothing more than a name is at stake such a change would make little sense. The new name signal that the Bio-medical model focuses on a too narrow conception of modern medicine. "Bio-medical" is an adjective implying that

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65 An important exception is an article by C. Boorse: Health as a theoretical Concept. Philosophy of Science 1977;44:542-73.

66 Holstein, BE; Iversen, L; Kristensen, TS. Medicinsk Sociologi (2.ed). FadL's Forlag 1992: p.19

medicine is restricted to a biological framework. Many discussions of the "Bio-medical Model" focus simplistic on one aspect of medical science revolting around the simple Error-in-the-machine-analogy. Though in many ways worthy of criticism I think medical science is more complex, dynamic and resistant than the Bio-medical Model pictures it. The name of "scientific" model focuses the attention on a broader field than the strict biological subject matter, and places medicine in the philosophical and scientific tradition. The scientific medical model that will be sketched in this and the following chapters could be constructed differently in a different context. I make no claim of completeness; however, the intention is to enframe a discussion about the anomaly of the placebo effect within a model that is as flexible and resistant as scientific medicine has shown itself to be, and to avoid the typical pitfall of the Bio-medical straw man.

The term medical model is not restricted to pure science, and the use of the term is not correlated to a special theory of the dynamics of medical history. In that respect it differs from a paradigm. I regard a medical model as a concentrated description of the "medical world view", the complex and often tacit concepts, way of thinking and organisation that enables a specific community to conceptualise and cope with disease.

Medicine and three levels of knowledge

Wulff[67] discusses the field of medicine and relates it to the distinctions science-technology-technic. Physics, for example, is a science that has the prime goal of unveiling rules that describe the nature of our physical surroundings. Engineers work on adapting the general physical theory on a special project, for example, building a hydroelectric plant. The engineers do research too, but have a fundamentally different goal than the physicist. Where science pursue truth for its own sake, an engineer solves a practical problem. Finally, the craftsmen who built the plant represent the technical dimension. A technician reproduces a learned conduct, a series of technics, but without asking any questions of way the technics work, without doing research. As an academic field medicine is special because it integrates all three levels of knowledge. The science dimension is in medicine represented by medical biology. The technology dimension is represented by researchers conducting clinical science, and finally most doctors are technicians in so far they work as clinical practicioners.

The analogy between medicine and the three levels of technology should not be driven too far. As Wulff mentions[68], the distinction is not only illuminating, but also problematic insofar it is based on a rather simple relation between science and technology. One misunderstanding is important to prevent. Clinical science is not just applied pure science, in the sense that the results of clinical science follow logically from the theories of human biology. The complexity of human biology, the biological variation, and constant

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67 Wulff, HR. The Philosophy of Medicine. Blackwell Scientific Publications Ltd. Oxford 1990: p. 40

68 Ibid: p.41

interaction between a variable environment and the human body makes clinical science more than applied. Of course clinical science makes use of the theories of human biology, but only as one of several founding elements. The deductions from theory are on a practical clinical level very unreliable. Another difference is that the high level of integration between the three levels of medical thinking make the notion of pure science problematic. Even the most remote part of biological research is influenced by the prime goal of medicine: ideally to create health which in praxis means treat diseases. Whereas the physicist never has to think in the means of practicability, it is always a relevant question in medical research to ask what is the practical potential of a particular research? This problem of practicability guidance is partly what Kuhn hints at when he mentions medicine as a field where his theory of scientific revolutions is incomplete.

It is fruitful to conceive medicine as a field in constant tension with itself, a tension between the two notions of objectivity and therapy, notions most clearly expressed in the scientific, respectively practical, dimensions of medicine. Therapy is historically the most important notion. As I discussed in the section on history of the placebo effect, medical history is full of examples of therapies that later have shown to be inert. The therapies regarded effective in a given time have mostly either been deductions from the theory of that time or treatments handled down through tradition. The social demand for a therapy is stronger that one normally thinks. Any society has institutions whose role it is to "cope" with disease, roles that are embodied in persons whose function it is to cure diseases, in some cultures he is called the medicine man or the shaman, in

others the physician. One could call this strong social demand for disease handling the therapeutical imperative. Regardless of the objective efficiency of a treatment most theories of medicine have a very few diseases categorised as incurable. The therapeutical imperative has to be confronted with very hard evidence of lack of efficiency before accepting a disease as untreatable. Probably the therapeutical imperative is the factor, beside the placebo effect, responsible for the "success" of most historical treatments. There is a very strong tendency to relate causally the treatment to the fact that the patient recovered. The *post hoc ergo propter hoc* fallacy is probably the most common fallacy in medicine: I was sick, I was treated, I became well. Ergo, the treatment cured me. The biological scientific dimension of medicine is primarily concerned with objectivity, and less with therapy. The construction of theories describing dys-function and disease which corresponds to reality is the main goal of the scientific dimension of medicine. This bipolarity between therapy and objectivity should not be conceived as exclusive. In an ideal situation the therapy is objectively effective; however, in the border areas or conflicting situations, the scientific dimension of medicine will tend to put weight on objectivity and the practical dimension put weight on the therapeutical implications. The field of medicine that tries to incorporate harmoniously both the notions of objectivity and therapy is clinical science. The scientific medical model concerns itself primarily with the two aspects of medical science, the biological scientific and the clinical scientific. In the following the two dimensions of scientific medicine are confronted with central notions from theory of knowledge.

Medicine as realism under empirical control

It is useful to distinguish between philosophical positions and philosophical levels of discussions. There are, at least, two important levels of philosophical discussion, the ontological and the epistemological. The ontological level focuses on how the world is in itself. Ontology can be understood as the knowlegde of what exists. Epistemology focuses on how we gain access to the world that exists, and is synonymous with theory of knowledge. The philosophical positions that I will make use of are realism and anti-realism, rationalism and empiricism. Realism is the ontological position that the world exists independently of any observer, that it is an objective phenomenon, not a kind of sham, a subjective dream or an illusion. Rationalism is the epistemological position that human reason can by itself grasp central features of the world. Pure reason has the ability to provide certain knowledge about the world, without any empirical initiation or control. Empiricism is the epistemological position that we really can not say anything about the world if it is not initiated and confirmed by empirical facts, by observation or experiments.

The following figure illustrates the relations:

Level of discussion	Philosophical position:	
Ontological:	Realism	Anti-realism

Epistemological: Rationalism Empiricism

How can contemporary scientific medicine be characterised by the notions mentioned above? One central feature of scientific medicine is that it is founded on a realist position. Both medicine and philosophy are the end products of a remarkable development that started in Greece about five centuries BC, where the Ionian philosophers rejected the religious or mythical explanations of natural events. They based their philosophy on two axiomatic principles. The first was their belief in the "first substance", a single fundamental physical entity from which everything derives. Their second assumption was that the diversity of nature causally could be explained as effects of that first thing. The idea of causes as such is part of every explanatory system religious, mystical or scientific. What was new was the more restrictive idea that events in nature were caused only by other natural events: *"The ruler of the world is whirlwind, that has unseated Zeus"* [69]. Causes and effects were part of nature and therefore explicable. Most of our knowledge about the Greek medical scientific tradition derives from the Hippocratic Corpus[70]. They document a reaction against the prescientific mythico-religious conception represented by the Ascleipian cult[71].

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69 A History of Western Philosophy (2.ed.). Harcourt Bruce Jovanovich inc. New York 1970: quoting Aristophanes on p. 0.

70 Hippocratic Writings. Penguin Classics. London 1983

71 The Cult of Ascleipus was a religious healing cult dominant in Greece about 6oo BC. The cult introduces "temple-cures", in special buildings for the sick, later developed to hospitals. The snake had an important role in the cult. One often practised therapy was to let (non-venominous) snakes lick the wounds of the sick. Later the role of the snake transformed from magical therapy to a symbol of scientific medicine: the snake that curles around the stick on the signs outside most pharmacies is Ascleipus' snake and stick.

The Hippocratic Corpus stress that also in the field of medicine causes are to be regarded as natural phenomena and not a question of Demons or Divine influence. The cause of a disease was explained by reference to for example climate, diet or lack of exercise. The treatise "The sacred disease"[72] on epilepsy begins with the following lines: *"I do not believe that the "Sacred Disease" is any more divine or sacred than any other disease but, on the contrary, has specific characteristics and a definite cause."*

The second feature of scientific medicine is a characterisation of the epistemological level. Before the empirical dimension of scientific medicine will be stressed it is necessary to present in more detail the notions of rationalism and empiricism. The philosophical dichotomy between rationalism and empiricism is useful to describe central differences between the clinical and biological aspects of medical science. Today the historical disagreement between continental rationalists (Descartes, Leibnitz, Spinoza) and the British empiricists (Locke, Berkley, Hume) may seem somewhat outdated, in the sense that their positions were so radical. The rationalists regarded the empirical refutation of human reason and innate human qualities as superficial, and the empiricists regarded the rationalistic approach as pure figment of the imagination. Seen retrospectivly both had something to say. The rationalist had a naive conception of the complexity of the world. In medicine Du Savages´ classification of diseases is a good example of a naive rationalistic approach. On the other hand they were right in insisting on the possibility of gaining knowledge of the world by

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72 See note 70: p. 237-51

reason. Today medical knowledge is quite at a different level, and few would doubt that the physiological and biochemical knowledge of the human body describes reality in a fairly precise way. The empiricists on their side were right in focusing on the limits of human reason and knowledge, and the emphasis on experiment.

If one looks at some contemporary medical theories normally considered non-scientific, for example homoepathy, they make no reference to spirits or religious forces, but must by characterised as realist theories. In what way do scientific medicine differ from for example homoepathy? One difference is that scientific medicine has a critical attitude to its subject matter and methods. Though the process of falsification probably is more complex than initially suggested by Popper, the knowledge that a theory or hypothesis can be wrong is an integrated part of the scientific process. At an epistemological level homoepathy is best described as a rationalistic theory. From a few central principles the therapy is deduced, but seldom systematically subjected to a thorough empirical testing. Scientific medicine does not only rest on a realist non-mythical conception of its subject matter, it also has a systematic empirical dimension, exemplified by the scientific experiment or the double blind trial. The logical positivists emphasise the empirical dimension, and try to construct a theory of science where the theoretical apparatus is strictly distinguished from the empirical dimension. Both Popper and Kuhn have showed that this simply is not how science is conducted. Empirical facts in medicine are not gathered randomly, on the contrary, they are a result of careful considerations within a specific theory. But the refutation of the

positivists should not produce an overkill, and initiate a general refutation of the empirical epistemological dimension in medicine. Modern scientific medicine can, with the notions here adopted, be described as *"realism under empirical control"*. [73]

Before the concluding presentation of the two medical scientific positions that will be confronted with the placebo effect, I will mention one more conceptual dichotomy that I will use. The notions of nominalism and essentialism are historically linked to the scholastic discussion in the 16th century regarding the true nature of the wafer. Was it really the body of Christ or just a name, a human invention? In spite the discussion's historically intense and fierce character most today think the question rather irrelevant. The terminology as I apply it to the discussion about the concept of disease, has little to do with its original role, and is intended to capture a central problem in theory of knowledge: to what extend do our description of nature capture an essence, nature in it self, or what Saul Kripke[74] calls "natural kinds", and to what extend is our description a human construction, a relative game of name giving. The discussion between essentialism and nominalism is a specific expression of the more general discussion considering the relevance of the ontological and epistemological level in the pursuit of knowledge. Where is the bottle neck of medical knowledge, on the ontological-essentialistic level, or on the epistemological-nominalistic level? Essentialism is sometimes called conceptual realism, but should not be confused with ontological realism.

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[73] See note 67: p.38

[74] Kripke, S. Naming and Necessity. Basil Blackwell. Oxford 1981: see for example pp. 116 and 134.

Ontological realism is the general metaphysical concept concerning the existence of an objective external world, whereas conceptual realism/essentialism is specifically concerned with the nature of notions, in the present context, mostly the notion of disease.

Plato, describing the ideal doctor in "The Republic", says:*"And it's disgraceful too to need a doctor not only for injury or regular disease, but because living the idle life .... (have) driven the medical profession to invent names for our diseases, like flatulence and catarrh..." "These new-fangled names for diseases are very far-fetched".* From an essentialistic position, Plato criticises his contemporary physicians for nomenalisticly inventing names for (in his view) non-existing diseases. As an example of a pure nominalistic position, one could mention Rousseau: *"There are no diseases, only sick persons".* [75]In modern medicine a nominalistic tendency is expressed for example in psychiatric diagnostic categories regarding abnormal sexual behaviour. Historically homosexuality is a disease entity. Most people today would regard that diagnosis as a pure nominalistic construction. The discussion sometimes gives the impression that only a nominalistic or an essentialistic position is possible. However, I want to make use of the notions in a different way, focusing on the tension between the two extreme notions, asserting that though different weight can be put on the epistemological or ontological level of a description one cannot omit or reduce the one to the other. I regard diseases as some kind of natural class, objectively describable to a certain

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[75] Quoted in note 67: p.78

extent. However, every description needs names, and the important question is what hides in the uncertainty of "a certain extent"?

Ontological realism has an affinity to epistemological rationalism, and ontological anti-realism has an affinity to empiricism. There is nothing principally wrong with a "diagonal" position, for example, to ontologically claim a realist position, and epistemologically an empirical position, however, the traditional association between realism and rationalism, and anti-realism and empiricism, initiates a tension in such a diagonal position. The characterisation of contemporary medical science as "realism under empirical control" is such a diagonal position. Thus medicine does not only contain a tension between a clinical scientific and a biological scientific aspect, but also on a conceptual level, contain a tension between its ontological and epistemological levels. The medical scientific model incorporates the two conflicting dimensions within contemporary medicine by conceiving scientific medicine as consisting of two positions: the Bio-mechanical and the Clinico-empirical position. The Bio-mechanical position is at a conceptual level primarily ontologically founded. With regard to the three levels of medical knowledge it circumscribes the biological scientific level. In praxis the Bio-mechanical position is mostly expressed in the laboratory, through biological scientific research. The Clinico-empirical position is at a conceptual level primarily epistemologically founded. With regard to the three levels of medical knowledge, it circumscribes clinical science, and is mostly expressed in clinical research on patients through clinical trials. Though the two positions, as will be clear, in many ways contrast with each other, it is paramount to regard them as positions within the same scientific model. The bio-

mechanical position does make considerable use of empirical research, and the Clinico-empirical position does not jettison the use of realist theories. What differs is not the general framework: realism under empirical control, but the emphasis put on realism and scientific objectivity within the Bio-mechanical position, and empiricism and therapeutical objectivity within the Clinico-empirical position.

In a previous section I described a medical model as the concepts, the way of thinking and organisation that enables a community to cope with disease. However, any analysis of a reasonable length including the complexity of concepts, routines and organisation expressed in a medical model would demand much more space than this thesis allows. I will restrict my approach to the two positions of the medical model to a conceptual analysis. There are many important notions that can be included in such an analysis. However, I assert that a number of central concepts constitute the "spine" of a medical model. The conceptual triad that I have choosen to focus on are: causality, disease and therapy. All three central concepts in a medical model are necessary and mutually support each other. However, different models and different positions have different weight on the concepts. The concept of causality is central both to science and philosophy and I will generally focus more on causality, regard disease as a supportive notion, and discuss therapy in more detail under the Clinico-empirical position.

Chapter four:

The bio-mechanical position

Generative Causality and Ontological Determinism

A realist sees causal connections as "something out there", as a feature of nature, as something real. The billiard cue hits the ball and this is the cause of its motion. This realist concept of causality, rooting back to the Ionians, was elaborated into its finest practical form by Newton. His revolutionary Philolosophia Naturalis Principia Matematica from 1687 reduces what seemed as remote

phenomena: the fall of an apple, the course of a cannon ball and the motion of planets to be effects of the same cause: gravity. Though very influenced methodologically by the empirical tradition of Galileo, his ontological position, as most scientists, was that of a realist. His notion of causality could be called a *generative* one. His laws of nature were realist descriptions of a cause generating an effect.

In medicine, the Newtonian notion of causality found its most precise formulation, and promising practical application by Claude Bernard[76]. In his "An Introduction to the Study of Experimental Medicine" from 1865 he emphasized the importance of experiments in medicine, and like the later positivists looked at physics as a guiding ideal. The bodily complexity was at the end of the day reducible to causal laws that could be unveiled in the laboratory. Bernard´s discovery of the glycogenic capacity of the liver and of the vasomotor nerves revolutionised physiology and supported his claim that biological events are causal in a similar mechanistic way as the movements of billiard balls, giving the name to the position: Bio-mechanical. There is a tendency in both Newton and Bernard to regard all natural phenomena as reducible to the effect of a few causes, preferable one single cause. The astonishing success of Newton's mechanics and Bernard's experimental physiology showed that this was possible, at least in some cases.

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76 The direct influence of Newton's theories on medicine was the "iatrophysical school": a medical theory conceiving biology as applied physics with little lasting impact.The concept of causality that Newton made use of , however, is parallel to Bernerds, two centuries later.

The philosopher who formulated most explicitly the ideas lying implicitly in the work of Newton was the Frenchman Laplace (1749-1827). In his "Essai Philosophique sur les probabilités"[77] he reflects on the possibility of a "world formula", a complete description of the world. He constructed a thought experiment featuring a Demon with incredible brain power and knowledge of Newton's laws. This creature would be able to know the initial conditions and the working forces of every physical body in the universe, and thus would be able to determine the future of the world. This *ontological determinism* was paired with an awareness of the practical difficulty of such a project, and Laplace claimed that man would have to settle with an incomplete statistical description, a position that could be called *epistemiological indeterminism*. It is probably not as great a paradox as it looks like that the formulator of the classical determinism also was the founder of the branch of mathematics known as statistics. Laplace developed this field on the basis of his experience with dice gambling.

Causally Defined Diseases

There was no single philosopher or doctor who formulated the corresponding Bio-mechanical concept of disease. The bio-mechanical nosographic[78] tradition grew stronger from the many scientific discoveries of the 19th century. Faber[79] divides several

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77 International Encyclopedia of Statistics. The Free Press. New York 1978: p.493 under "Laplace".

78 I use the word "nosography", as a term not restricted to disease description but in a broader meaning the concept of disease.

79 Faber, K. Nosography. P.B. Hoeber. New York 1930.

phases in the evolution of disease classification and the disease concept: the patho-anatomical, the physiological, the microbiological, and the genetic. However, I will reduce the different approaches to two fundamentally different ways a disease entity is defined or essentially described from a bio-mechanical position. Some diseases are what can be called "clinical syndromes": diseases whose characteristics are the conjecture of the clinical symptoms of a patient. Crohn´s disease or multiple sclerosis are examples of such syndromes. They are empirically defined with no reference to any underlying causes. Other diseases are so called "causally defined diseases". The paradigmatical example is a bacterial infection. The works of Koch and Pasteur supported Bernard's old ideal of the single cause. The cause of pulmonar tuberculosis is the bacterium that infects the lung: mycobacterium tuberculoses. The bio-mechanical position conceptualises disease as the error-in-the-machine, and though not essentially a part of the position, there is a strong tendency to emphasise the singular: error, not errors.

From a bio-mechanical point of view the clinical syndromes have less scientific status then the causally defined diseases. In the bipolarity between essentialism and nominalism, the classical position is associated with the essentialism. There is a sharp distinction between the symptoms and the cause of a disease, and correspondingly between the illness and the disorder. The illness is what the patient feels, the pain and discomfort, whereas the disorder is the underlying pathological process, the "disease-in-it-self". The impetus of the causally defined diseases pushes the balance between disease and illness in the favour of illness. In the

process of the objectivisation of the illness, the subjectivity of the patient, his ill-ness, loses importance.

The Bio-mechanical position has difficulties explaining the nature of human psyche and its influence on disease. In later chapters I will discuss in detail the mind-body problem here expressed, and restrict myself to note that the Bio-mechanical position is associated with the traditional Cartesian dualism. Here the psyche is acknowledged as of importance to disease, but not to science. The subjective experience of ill-ness is something priests and philosophers should handle, but has little interest for scientific medicine.

One cause-one cure

The bio-mechanical notion of therapy is in a way very simple. The whole idea of the strict deterministic disease description can be seen as structuring a clinical situation were the complexity of a disease is reversible by a single pill. The model revolves around the assumption that to the single cause behind a disease there corresponds a singular causal therapy. The cure for tuberculosis is the antibiotic, that kills the mycobacterium: streptomycin. Therapy is closely associated with theory. A therapy distinguishes itself from a treatment by relying on the guidance of a theory of the nature and causes of the disease to be stopped. One can call the ideal of the classical scientific position for *curative* or *causal treatment* The surgical removal of an inflamed appendix or the treatment of tuberculosis with drugs that kill mycobacterium tuberculoses are regarded as curative therapy. When you have

treated the cause of the disease you have cured the patient. However, this ideal is often not practicable. What can be done is to treat the pain relating to an illness. This is called *palliative treatment,* or more general, when other symptoms than pain are targeted: *symptomatic treatment*

The placebo pill as an imitation- the placebo effect as a challenge

The placebo effect is a therapeutical result of the general clinical setting and the interaction between doctor and patient. The placebo is a sham treatment, often in the form of a inert pill. Such a treatment is, if not acceptable from a Bio-mechanical position, then at least acknowledged as a sham, an imitation or distorted reflection of the proper sort of medicine. A sugar pill is still a pill and imitates, and therefore reflects and confirms, the classical ideal of one cause, one cure. It is probably no coincidence that the concept of a placebo treatment grew out of a classical scientific tradition. The placebo *effect* as such is much more problematic. The ideal of the somatic objective medicine is that the doctor and the patient as individuals essentially are irrelevant. The doctor is seen as a professional who treats disorders, not individuals, and he could in principle be swopped by a colleague with the same qualifications. The placebo effect's emphasis on the clinical setting challenges this ideal. The real placebogenic complex has to do with the clinical setting and the personal interaction between doctor and patient. Entities that, from a Bio-mechanical position, ought to be utterly irrelevant to any therapy.

Doubt about the Bio-mechanical concepts

Regardless of what aspect one focuses on, there is a disharmony between the placebo effect and the Bio-mechanical position. There is no organ or cell in the biological machine of man that, in any reasonable degree of detail, can explain the placebo phenomenon. The concept of one cause-one cure is, as well, very remote from the multi-causal placebo effect. The importance of the personalities of both doctor and patient, the influence of the psyche of the patient are all phenomena that contrasts the Bio-mechanical position. When a part of a medical model, or in general a theoretical prediction, is confronted with an empirical phenomenon that the theory is unable to account for there are, in principle, two strategies one can adopt. The first is a defensive strategy where, in this case, the Bio-mechanical position is modified to fit the facts. The disharmony between the placebo effect and the Bio-mechanical position makes this strategy plausible and both Hahn and Brody regard the placebo effect as anomalies. I agree with them in so far as the the placebo effect raises severe doubt about the completeness and usefulness of the Bio-mechanical position.

However, another possible strategy, with regard to a disharmony between empirical facts and theory, is to criticise the empirical foundation. In an attempt to immunize the Bio-mechanical position several offensive lines of arguments can be used. As I illustrated with the cartographic definition, the placebo effect can be regarded as either not "real" or it is criticised of only being a unspecific, and therefore undesired, therapy. Shapiro's placebo definition contained the ambiguous term “unspecific”. The placebo effect is an unspecific effect, where for example the effect of streptomycin is specific on

mycobacterium tuberculosis. In the next chapter I will elaborate this more; at the moment it is sufficient to point out that "specific" in the bio-mechanical sense means causally explicable in a deterministic sense. A specific therapy is here synonymous with a causal therapy. The placebo effect is regarded as unspecific, as only affecting symptoms. It is at best harmless as it does not influence the biology of a disorder, and at worst harmful as it can disguise relevant symptoms. Such attempts of ad hoc immunization of the Bio-mechanical position are, after a review of the empirical material on the placebo effect, in themselves unplausible and raises not only severe doubt about the Bio-mechanical position as such, but also about the concepts that it is built on: the one cause-one cure notion, the strict distinction between causal and symptomatic therapy, and between disorders and illness. The Bio-mechanical position is left with a serious problem. The Error-in-the-machine analogy has great difficulty in incorporating the influence of the psyche on disease in general.

Conclusion

Seen from the Bio-mechanical position therapy and disease are not influenced by the patient's perception of his situation, they are essentially objective, natural kinds. The cure is based on the isolation of a cause and a physical or pharmacological therapy thwarting that cause, not on a unspecific inter-personal relation between a doctor and a patient. The placebo effect represents a severe anomaly for the Bio-mechanical position. The possible attempts of ad hoc immunization of the position are not plausible.

The usefulness of the concepts on which the Bio-mechanical position stands, is doubted severely.

Chapter five:

Placebo and The Clinico-empirical position

Succession causality

David Hume is possibly the most important philosopher in the field of causality. Before him the concept was regarded as self-evidently real, maybe complex to describe because, in a specific situation, we do not posses all relevant facts; but at a philosophical level causality was firmly and unchallenged rooted in the palm of the realists. David Hume criticises the realist concept of causality and introduces an empirical alternative, known as *"succession causality"*. In Hume's "A Treatise On Human Nature" from 1740 he undermines the realist conception of causality with an empirically minded argumentation. He says that the only relation we can be sure of is that the "effect" follows successively from the "cause". Cause and effect are two events that we customarily relate to each

other in a specific way in which the first is responsible for the second. When two events are spatially and temporally conjoined so that one succeeds the other in a regular way we speak of causality. However, the necessary connection traditionally attributed to causality is nothing more than an idea, a felt expectation of the mind. Hume makes use of the so called induction problem to support his claim that the necessary connection between cause and effect is only an idea: not "something out there" but "something in us". That event A always has been temporally and spatially succeeded by event B can never make it logically valid to conclude that A in the future always will cause B. In the end of the section in the Treatise where causality is discussed Hume offers a list of rules used for practically judging relations of cause and effect: 1. Cause and effect must by contiguous in space and time. 2. The cause must be prior to the effect and 3. There must be a constant conjunction between case and effect.

Hume was immensely impressed by Newton, and his whole philosophical project can be seen as an attempt to apply the inductive and critical method of natural science on theory of knowledge and moral philosophy. However his succession causality is clearly fundamentally different from that of Newton and Bernard. They might have called themselves empiricists and were so in a methodological way, but when it came to the underlying metaphysical position grounding their practical research they were realists. Hume´s analyses did not have much influence on the practical scientific level. In a philosophical context however his importance was immense, partly through his influence on I. Kant.

Causality and quantum mechanics

In a scientific context the classical determinism was unchallenged as an ideal until early this century. Physics, the hard core natural science, then discovered that in the micro-cosmos of atoms and elementary particles the classical way of describing causal relations was inadequate. Bohr and Heisenberg were the main creators of quantum mechanics, as the new field was known. It challenged some of the basic assumptions that Newton's classical mechanics was built on, and revolutionized the concept of causality. One of the corner stones of the quantum theory is the Heisenberg Uncertainty Relation. It can be formulated as:

$P * Q = h.$

"P" is the coordinates of position and "Q" of momentum of subatomaric particles as for example an electron, whereas h is the constant speed of light. The consequence of the formula is that with the greater certainty or determinism we measure for example p the more indeterminate or uncertain will our knowledge of q be. The causal connection of the particles in question is of such a character that the classical deterministic description is unsuitable. The highest degree of precision for that particular subject matter is represented by the statistical formulae describing the possible events. We can not measure in a deterministic way both the momentum and the position of an electron, only describe with statistical uncertainty their relation. The importance of the Heisenberg Uncertainty Relation for the theory of knowledge is

twofold. Firstly, it exorcises the Demon of Laplace, and silences the classical determinists. The only field of human knowledge where classical determinism had been practically endorsed on a grand scale: physics, now introduced a whole field, where the causal connections were of a fundamentally different character. It was not longer only a practical problem of gaining access to the forces and initial conditions of every physical body. It is on a theoretical level in principal impossible. Secondly, it focused attention on the nature of statistical description, or probability itself. Since the days of Laplace statistical methods were used many places, also in medicine, but there was a tendency to regard them as an incomplete description. Statistical approaches to scientific facts were seen as an incomplete description of nature, as an epistemological waiting place before the real description was attainable. The new quantum theory made that view problematic. The philosophical interpretation of the quantum theory can be divided in two main groups[80]. The first position, represented by Einstein, gives it an epistemological status, it is our incomplete description of a fully determined nature. The second position gives it full ontological status, and is represented by the similar, but not identical views of Bohr and Heisenberg. Quantum theory is regarded by Heisenberg as an unavoidable interaction between nature as object and the human subject. The researcher changes nature in his act of observing it. The researcher is not any more describing an observer-independent reality. The observer-dependence is, on the contrary, part of reality.

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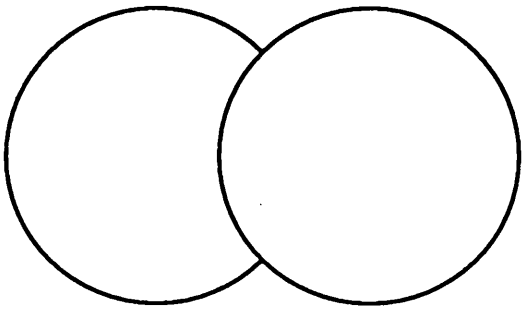
80 Petersen, A. Quantum Physics and the Philosophical Tradition. MIT Press. Cambridge 1968

Necessary and sufficient conditions

A classical way of describing a causal relation is to define the necessary and sufficient conditions for an effect. The clarification of the terms is usually done by referring to a black box model where the causal relations are unknown to us and where we can only observe the events of cause and effect. It could for example be a coffee machine. I insert a coin in machine A and get a cup of coffee. This happens every time I insert a coin and does not happen if I don't insert the coin. The insertion of the coin is a necessary and sufficient reason for my cup of coffee. However a machine B is different in a very unpopular way. Sometimes, for example one out of three trails, it does not produce the wanted fluid. The coin insertion is a necessary, but not sufficient cause. A third machine differs from the two previous. It is very popular because beside serving a cup every time a coin is inserted, it sometimes produces coffee without a previously inserted coin. The coin insertion is here a sufficient, but not a necessary cause. In other words: the effect in question is always preceded by the neccesary cause, that, however, is not sufficient *allways* to initiate the effect. The sufficient cause, on the other hand, is always followed by the effect, which however, can be initiated without the specific sufficient cause.

The relation can be illustrated by a Venn diagram:

N N S S



The area N represents the situations exemplified by machine B: Every coffee was proceeded by a insertion of a coin. The area S represent the situations exemplified by machine C: every coin was followed by a coffee. The area N S represent the working of machine A: every coin insertion is followed by a coffee, and no coffee is not produced without a coin. This area represents the classical deterministic ideal of causal relation.

However clarificatory the notions are in rather simple black box examples as above, every-day situations, and also many medical situations, prove far too complex to be adequately described by them. Lung cancer and tobacco smoking have been linked together since the early fifties and represent one of the major health problems in the world. It would be a grave misunderstanding to regard the applicability of the notions of necessary and sufficient causes as a kind of indicator for the importance of a causal relation. Smoking is neither a sufficient nor necessary cause for lung cancer. The majority of smokers do not get cancer, and of those who get lung cancer a minority have never smoked.

Causal fields and inus-factors

A different approach to causality is represented by John Anderson[81]. In an essay on difficulties with J.S. Mill's concept of causation he introduces the term "causal field". His starting point is interesting as he can be regarded as describing the notion of causality from an every day language approach, and therefore differs from the starting point of most others who relate causality to science, often physics. Instead of focusing on the linear causality between event A and B, a coin causing a cup of coffee, he in the phrase "causal field" includes every causal interaction that has influenced the event one is interested in. The event one is interested in often relates to what is the abnormal outcome of a usually normal causal complex of events. Anderson claims that every causal statement is built on a question: what caused X? X is an event that sticks out compared to the normal causal field, for example the burning of your house. It would be absurd to ask why the house did not burn down today, because the house does not normally burn down. It is a part of the normal causal field that the house does not burn. If the house accidently does burn down, the question becomes very relevant: why did it burn down? Analogous to the difference in effect, the relevant causes that might be listed, would be the ones that are abnormal compared to the causal field. Maybe some would note that there was a gas leak, or that some children were experimenting with the art of sending smoke signals by making a bon-fire on the roof. However, no one would think of noting that the atmosphere consists of 20 % oxygen, because it is a

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81 Anderson,J. The Problem of Causality. Australasien Journal of Philosophy, XVI 1938.

fact that is part of the (tacit) normal causal field. It is interesting to note that in a black box situation the presence of oxygen would count as an necessary but not sufficient cause for any fire. If someone, however, in the basement had illegally stored pressure tanks containing pure oxygen, such a fact would, if the tanks exploded and caused the fire to escalate, be regarded as relevant to any legal prosecution after the fire. The juridical concept of cause is, by the way, very close to the notion here sketched, as described by Hart and Honoré[82].

The causal field notion is also important for J.L. Mackie who, in his "The Cement of the Universe",[83] suggests the notion of inus-factors. Inus-factors are insufficient but necessary parts of an unnecessary but sufficient causal complex. In other word, they are any part of a causal relation that, if not present, would change the outcome or effect: they are non-redundant factors. The particular causal complex one is interseted in contains a series of events causally linked resulting in an effect contrasting the normal causal field, for example the gas leak leading to a burned down house. The single inus factor is an insufficient but necessary condition for the effective causal complex. The causal complex is initself unneccessary, other possible alternative series of events are possible, but sufficient for the outcome. The weakness of the term is that it is immensely open ended, there normaly are very many non-redundant factors. Smoking is an inus-factor in relation to lung cancer. It would be an Sisyphean labour to exhaustively list every

82 Hart, HLA & Honoré, AM. Causation in the Law. Oxford 1959.
83 Mackie, JL. The cement of the Universe. A study of causation. Oxford University Press. Oxford 1974.

thinkable inus-factor relating to for example lung cancer. Again oxygen in the atmosphere would be one, as it is necessary for smoking a cigarette. The list could continue ad absurdum and probably ad libitum. The strength of the term is that it emphasizes the strong connection between what we think is a relevant cause and the framework of the whole project of asking a causal question. The selection of a cause in a medical context mirrors what the medical society thinks is most relevant to the strategy that is to be implemented. It points out that in many situations there is no evident way of distinguishing an event as a cause from a condition. The interesting question still is what causes a disease, but the Clinico-empirical formulation would in stead be: what are the most important causes?

The illusion of one cause-one disease

Mackie's analysis is relevant when looking at the concept of disease. The bio-mechanical nosographic ideal revolves around the concept of a causally described disease: to one cause there correlates one cure. The paradigmatic example is the bacterial infection. However, we know that the majority of persons infected with, for example, TB are immunologically able to counter the bacterium, and never get sick. In the middle of the last century the risk of exposure to the mycobacterium during a life span must, in certain areas, have been close to 100 %. Its status as a cause can thus be compared with the presence of oxygen in the previous example of the burning house. The presence of mycobacterium is a necessary but not sufficient condition for tuberculosis. Defining the cause of

tuberculosis is to construct your point of view, selecting one or more factors from the causal complex leading to the disease, call them causes and the rest conditions. A microbiologist will present the bacterium as the cause, a family practicioner engaged in social medicine will point out bad housing as the cause, and finally a immunologist will tell you that the cause is to be found in a weak immune system. With this I am not trying to criticise scientific pursuit of causes of diseases, only showing that the ideal of a fully causally described disease is impossible to practice. Even the paradigmatic causally described disease: an infection, reveal itself as multifactorial. Its "causes" are relative to the perspective of the researcher.

In contrast to the Bio-mechanical concept of disease, an Clinico-empirical position will have a strong affinity to nominalism. The patient as a subjective individual gains importance as the notion of causally fully described diseases reveal itself as an illusion. The natural classes of diseases are not so natural after all when the central features change character with the intentions of the interested researchers. The extent of indeterminism changes from what a realist regards as irritating statistical uncertainty, to a central part of the abstract notion of a disease. When the "real" existence of an illness is discussed, the evident real existence of the patient becomes a point of security. What a physician is treating is not a disease, but a person. The disease is only a conceptual tool in the pursuit of an effective therapy for that person.

Pragmatic Therapy

The Bio-mechanical position strictly distinguishes between "specific" and "non-specific" therapy, and regards "specific" therapy as synonymous with causal therapy. However, "specific" also has another meaning attached to it. Streptomycin is regarded as specific therapy, whereas good housing, and diet are regarded as non-specific. In other words a non-specific therapy helps in a general way, whereas a specific therapy cures one or a few illnesses or symptoms. This nosographical, or scope limiting, aspect of "specific" can be regarded as the empirical interpretation of "specific". There are several unspecific therapies. The most well known is what is called "conservative treatment". This is a regime where no specific surgical or medical action is taken, but where the healing powers of the body are supported by a number of unspecific treatment factors as for example hospitalisation, rest etc. A specific therapy is regarded as more efficient than an unspecific. This is generally true, but the point is that they are intimately intervined, and at least the specific treatment factor cannot be seen alone. The effect of a specific therapy is based on numerous unspecific factors, in a way analogous to a basis-superstructure relation. The specific therapy of TB, streptomycin, is build on the basis that the patient rests, gets enough to eat, is in the hospital where the hygiene is good etc.

The Bio-mechanical position insists as well that there is a fundamental distinction between causal and symptomatic therapy. Though for some purposes the distinction is useful, the Clinico-empirical position would claim that the distinction is not fundamental, because it is relative, what can be called a causal therapy. A microbiologist would regard a streptomycin cure for TB

as causal therapy, but an epidemiologist would call it symptomatic treatment, because he focuses on different causes (bad housing etc). What is regarded as causal therapy is relative to the point of view of the researcher, in the same way as what is regarded the cause of a disease is relative to the point of perspective.

The Clinico-empirical position does not say that there is no difference between treating a fractured arm with pain killers or reponing the two fractured ends. However, it does not regard good therapy as synonymous with causal therapy. A Clinico-empirical position will insist on the perspectivistic aspect of what is regarded as causal therapy. When a Bio-mechanical rock-bottom concept is relativised an alternative empirical notion must take over as "anchor". There is in the Clinico-empirical position embedded a pragmatic concept of therapy: Regardless of the theoretical explanation, whatever helps, whatever works, is a therapy, and is worth pursuing.

Therapy and Manipulative Capacity

From a Clinico-empirical position it is not interesting whether or not psychological or social factors influence disease. There is no sharp distinction between biological and other causes, just as long as a causal relation has been established. The necessary question then is, on what grounds an empiricist will make his therapeutical priorities, what makes one therapy better than an others? There are several different reasons one could focus on, but in this context I will focus on two. The first is that the effect of the treatment must

be substantiated firmly. The second is that we are capable of manipulating in such a way, that in the therapeutical process, we do not create a worse situation than we started out with. In this section I will focus on the manipulative aspect, and later return to the necessity of proper empirical substantiation.

Health is always regarded as something valuable, sometimes one gets the impression that it is the only value in medicine. However, consider if health actually was the chief good: the knowledge of society's prime value is embedded in the physicians who would get a kind of Philosopher King status. Smoking will be punished by hanging, food would be regulated by a personal commissioner of diet, drinking would result in compulsory involvement in clinical trials. Traffic would be regulated so to avoid any traffic deaths: speed limits down to 30 miles an hour, a policeman situated on every corner, and all cars and road sides protected by a thick layer of rubber. Most people would be horrified by the thought of living in this Utopia of health. With this little thought experiment I am emphasizing the fact that behind every therapy there are considerations of non-scientific nature. A therapy being assessed with regard to its possible implementation will, apart from its clinical significance, always be measured by economical end ethical-political standards. The expense and inconvenience to the society as a whole connected to, for example, placing a policeman on every corner, overrules the importance of the decrease in traffic caused deaths. The necessary restriction of personal freedom in the Utopia of health would for many be ethical and politically unacceptable.

Apart from the moral or political factors effecting the usefulness of a therapy, there is also a practical level to be addressed. Imagine that an immunological defect is a inus-factor in the etiology of a hypothetical form of hepatic failure. The immunological defect is not therapeutically potent if procedures are not invented that actually are able to counter that defect in a reasonable smooth manner. The difference between penicillin therapy for pneumonia and liver transplantations for hepatic failure illustrates this. Giving a patient a tablet of penicillin is, at a practical level, easier than the technical complexity of whole organ transplantations. The difference in practicability alone makes penicillin a much more attractive therapy. If a pharmacon was invented that reversed the hepatic failure in question, the transplantation would be abandoned.

The Placebo Effect and necessary/sufficient conditions

The placebo effect cannot be incorporated in the Bio-mechanical position, and creates severe doubt about the usefulness of the conceptual apparatus of that position. However, the situation is different when it comes to the Clinico-empirical position. In the rest of the chapter I will show that the Clinico-empirical position on important areas provides a congruent conceptual frame for the placebo effect. The following section will discuss the implications of the placebo effect on the causality notions elaborated previously.

Is it possible to describe the placebo effect in terms of necessary and sufficient conditions? Are there, to start with, any sufficient

conditions for the placebo effect? The patient's anxiety and the doctor's professional personality could be candidates. However, beside the vagueness of the used terms, it is implausible that anxiety alone or even both factors together is sufficient for initiating a placebo effect. Possibly they are conspicuous conditions but not sufficient in the strict sense. What about necessary conditions? A vague list could include some of the aspects normally used to describe the placebo effect, for example the existence of a clinical setting, a patient, a doctor etc, but would have the character of a forced reformulation with little new information to present. The classical terminology is, not surprisingly, difficult to apply systematically in an illuminating way; however, one aspect is worth dwelling on. A necessary condition for the placebo effect is that the patient is *conscious*. In that aspect the placebo effect differs from most other treatments. If a patient treated for TB was unconscious it would make the clinical process of diagnosis more difficult, but not, in principle, effect the outcome of the therapy. He would as well be treated by unspecific therapeutical factor, as he is in hospital, is washed and otherwise taken hand of. All of the therapeutical field of scientific medicine, except the placebo effect, would work on a comatose patient. One fundamental difference between therapy in general and placebo is that dealing with a person not conscious of the clinical setting, being comatose or otherwise unconscious, shortcuts the placebo effect.

The only other therapy also based on the patient's consciousness is psychotherapy. I omit any attempt of discusing whether psychotherapy is placebo or not. The placebo notion is born out of a scientific world view as a kind of negative reflection, a distorted

image, and is a very general term applying possibly to any clinical situation. It is as well associated with a Clinico-empirical position. Psychotherapy, on the other hand, is born out of a Freudian tradition, has a much narrower scope and is intimately connected to the theoretical apparatus of dynamic psychology. It is, as well, close to a non-empirical realist position. To compare the one with the other in detail will be interesting when we know more about the underlying mechanisms, but at the moment I think such an attempt quickly would muddle the general discussion of placebo[84].

The placebo effect, though difficult to describe satisfactorily in the classical terms of necessary and sufficient conditions, fits the concept of inus-factor. Usually inus-factors are used to analyse the causal complex leading to a disease, however, there is nothing principally wrong with the application to the causal complex of a therapy. The question could be asked: what are the insufficient but necessary parts of an unnecessary but sufficient causal complex leading to a placebo effect? Or shorter, what are the inus-factors that initiates a placebo effect? The specific factors to mention will be the ones described earlier, however there is no terminological difficulty about, for example, the status of patient anxiety. It is highly uncertain whether patient anxiety is a sufficient condition, but not whether it is an inus-factor. The different causal factors constituing the placebogenic complex are, when described as inus-factors or non-redundant conditions, acnowledged as important causal factors. That they at present are wagely understood makes a

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84 I discuss Grunbaum's article on psychiatry and the placebo effect in chapter two.

selection of one or several factors as the most important ones a rather random process.

Placebo and pragmatic therapy

The clinically most important symptom influenced by the placebo effect is pain. Pain perception, regardless of its acute or chronic character, is radically changed by the placebo effect. This factor alone is of great clinical importance. Pain is possibly the single most important symptom in medicine, it is part of almost every disease. However, placebo also affects diseases that usually, from a bio-mechanical position, are categorised as causally defined. There is little doubt that the most important type of diseases influenced by the placebo effect have a reasonable large psychological or psycho-somatic component, however, a causally defined disease as peptic ulcer is often cured by the placebo effect. The distinctions of specific/unspecific and causal/symptomatic are highly problematic, as discussed previously in this chapter. They do not provide a good conceptual frame for the placebo effect either. From the point of view of the Clinico-empirical position it would be more appropriate to say that the placebo effect is a part of the broad therapeutical field, that is available to a physician on the line with hospitalisation, rest, penicillin, surgery etc. Off course it is a problem that the mechanisms of the placebo effect are so poorly understood, however, the Clinico-empirical position is more interested in the therapeutical potential than in the theoretical coherence. The Clinico-empirical position's acceptance of a theoretical biological ignorance is compensated by the paramount importance connected to the empirical substantiation of a real therapeutical effect. The

empirical documentation becomes the positive scientific benchmark of the Clinico-empirical position. In the second chapter I discussed some methodological problems concerning the classical articles on placebo, the next section will touch on the possibility of a trial specially designed to measure the placebo effect.

A trial measuring placebo

Can one construct a trial where the placebo effect is measured in itself, and isolated from any pharmacological effect, natural remission or other factors? Most documentation of the placebo effect has been done by extrapolating results from trials that were intended to measure a pharmacological or surgical effect, and as I discussed in chapter one, there are certain flaws connected to such an approach, primarily concerning the lack of systematic distinction between the placebo effect and the natural remission. A trial that is designed to measure the placebo effect must incorporate a way to overcome this structural bias. Assume that we have a group of patients that randomly are allocated in a control group and a placebo treatment group. The basic idea of such a trial would be to induce a placebo effect in the treatment group and to make sure that a placebo effect is not initiated in the control group. In that way the spontaneous remission (and other factors) would be checked for by subtracting the effect outcome in the two groups. The size of difference would be the real size of the placebo effect. The problem is, however, that the placebo effect is not initiated only by a sham pill, but by the clinical setting, patient anxiety, physician´s expectancy etc. In other words it seems extremely

difficult theoretically to ensure that a placebo effect is not initiated in the control group.

A methodologically less satisfactory, but practically implementable approach, consists in defining the placebo group as a placebo-maximising group and the control group as a placebo minimising group. The physicians involved would then in short behave by two different strategies. The half of the patients would be treated in a way that one believes do not initiate a placebo effect. The patients would be superficially examined, the doctor would try to make the impression he does not believe in the treatment etc. The other half of the patients would be treated in a way that is believed to enhance a placebo effect, they would be examined thoroughly by an enthusiastic doctor with great faith in the treatment. However, the placebo minimising group would still potentially be affected by a placebo effect. They are a part of a clinical setting and some of the older patients would even expect a "proper "doctor to behave like that. To be absolutely sure one has escaped the placebo effect, and thereby created the basis for an placebo free control group, is impossible. One is forced to look at the patient's symptoms without the patient knows he is in a clinical setting. Is that possible? Well, without getting in to the massive ethical problems of such an approach, I see just as severe methodological problems. One cannot practically gain detailed clinical information without the patient knowing about it. A rather desperate avoidance strategy would be to use unconscious patients. Unconscious patients cannot react with a placebo effect. However, this would introduce a selection bias, because one will never be certain that what makes the patients unconscious does not in some way effect the clinical parameters

focused on, thereby introducing a structural difference between the control group and the placebo group. An methodologically satisfying placebo measuring trial seems to be impossible to design. The control group can never fulfil the necessary demand that it must be impossible to induce a placebo effect there.

The epistemological status of the placebo effect in medicine resembles on important areas the status of Heisenberg's uncertainty relation in physics. Heisenberg's own philosophical interpretation of his relation can be summarised as follows: the apparatus necessary to measure entities as the momentum of electrons interact with the electron in such a way that its momentum or position changes. The process of objectivisation in itself initiates subjective or indetermined behaviour of the electron. A fundamental new aspect of quantum mechanics is the importance the experimental setting obtains. In one setting the electron behaves as a wave, in another setting it behaves as a particle. The subjectivity of the researcher, expressed through his choice of experimental setting, becomes a part of the theory. In a similar way is it in principle impossible to measure the placebo effect in itself. As discussed in the previous paragraph, the only thing one can quantify is the difference between a small and a large effect. In the process of measuring the placebo effect, what one wants to measure, is enhanced. The role of the physician with regard to the placebo effect is analogous to the role of the researcher with regard to the uncertainty relation. The clinical setting gains a radically new importance through the placebo effect. What used to be a framework for a working process aiming at a pharmacological or surgical therapy suddenly, in certain situations, becomes

therapeutical itself. The experimental setting of quantum mechanics and the clinical setting of the placebo effect are analogous in so far both are examples of a scientific "setting" that is not a passive frame but an active component of the measuring or therapeutical process.

Does this affect the realist foundation of the Clinico-empirical position? At a first glance the immeasurability principle seems to be a problem. Realism is the position that the reality exists independently from the fact that it is being observed or can be observed. In the process of observing the placebo effect, reality, in this case the placebo effect, is manipulated, is not independent. However, one thing is that it is manipulated or changed by the observation process, another thing is if it can exist independent from it. The placebo effect is mostly initiated in a clinical context with no intention of observing the phenomenon. Historically a multitude of therapies were given that later have been interpreted as placebos, but, which at the time, were regarded lege artis. Observing the placebo effect, through a clinical trial, is not a necessary condition for its initiation. The immeasurability of the placebo effect is in accord with a realist foundation. What about the empirical foundation? The immeasurabillity principle of the placebo effect contrasts the bench-mark of scientific credibility of the empirical position. That the subject matter of interest elopes a concise empirical substantiation is a problem that the Clinico-empirical position has to address. One possible avoidance strategy is to redefine the placebo effect so it becomes measurable, operationalize it. One could redefine the placebo effect negatively, and regard it as the therapeutical effect in the control group of a

double blind clinical trial. In that sense we would have a fixed empirical focus, however, it would be a muddled and uninteresting focus. The intriguing character of the placebo effect is that it changes the status of the therapeutical meeting. Without the placebo effect a therapeutical encounter is a form into which the real treatment can be filled. The placebo effect changes this strict division between form and content because it insists that the clinical encounter as form has a therapeutical content. To redefine the placebo effect to a measurable entity would fit with an empirical position, but muddle the specific character of the placebo effect, because it would be pooled with other therapeutical factors as for example natural remission.

Placebo as practicable therapy

The second feature of the placebo effect that the Clinico-empirical position has certain problem addressing is the practicability of the placebo therapy. Important from a Clinico-empirical position is the manipulative capacity of any possible therapy. The reshaping of Africas economy would, for example, have a huge impact on health in general and also on the AIDS and TB epidemics. It is, though, extremely naive to suggest this as a therapy. It is, at least from a medical position, impossible to manipulate in a practicable manner. The question of this section is whether the placebo effect is a therapy possible to manipulate, or a phenomenon academically interesting, but therapeutically impotent?

To give a placebo as for example a sugar-pill, presents no practical problems (lots of ethical problems, however). As argued before, the

pill in itself is not placebogenic, and must be distinguished from the placebo effect. The placebo effect must be subscribed to the placebogenic complex. The question important to ask for the Clinico-empirical position is then how a physician can enhance the placebo effect? There has been done very little work on that question, and at the moment it would be to push the subject pas the limitations of the knowledge to try to say something substantially. The articles on the subject[85], however, mention two general features related to a high placebo effect. The one is the patient's anxiety. The more frightened and nervous a patient is the more liable he is to be affected by a placebo. The second factor is a paternalistic and enthusiastic physician, who believes strongly in his therapy, signals confidence. Noting the subjective quality of the placebogenic complex, the factors mentioned are fruitful as rules of thumbs, but can disguise the complexity of the individual process. It would be too superficial to conclude that if the doctor takes his time, explains the situation and create an anchor of certainty in a stressful moment of illness, a placebo effect will be enforced. There needs to be done much more research on the specific placebogenic elements of the clinical setting. At the moment there is no reasonable security that a certain behaviour from a physician or a certain design of the clinical setting are sufficient for the initiation of a placebo effect in a patient.

Conclusion

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[85] See for example: Schindel, L. Placebo und Placebo-Effecte in Klinik und Forschung. Artzneimittelforsch. 1967;17:892-918.

The placebo effect corresponds in important areas to the concepts of the Clinico-empirical position. Most important is that the placebo effect as a multicausal phenomenon can be framed in terms of inus-factors. Also the pragmatic concept of therapy and multicausal disease conception correlates to the placebo phenomenon. So far the placebo effect is not only born out of the Clinico-empirical position, through the terminology and methods of clinical trials, it also is a phenomenon that in important areas reflect the concepts of the Clinico-empirical position. However, there are two features of the placebo effect that the Clinico-empirical position have to address. The first is that the practical therapeutical implications of the placebo effect are minimal. The second is the impossibility of designing a trial that can quantify the placebo effect.

The manipulative capacity of the placebo effect is enhanced by the fact that it is basically a question of a relation between two persons in a clinical setting. Maximising the placebo effect is not analogous to changing the economy of Africa. Its problem is, though, that the placebogenic complex possibly is so complicated, that simple rules of thumbs will be inadequate. The complexity of the placebogenic situation is intimately connected to cultural, psychological and individual factors. The objectivity of natural science will have difficulty grasping a fruitful level of precision. However, regardless of the strategy of research, if more factors enhancing the placebo effect are found, or the dynamic of the placebogenic complex is described, the manipulative capacity of the therapy will be much greater. That we at the moment do not know enough about the placebogenic factors, from an empirical point of view, is not so important, if the knowledge is regarded obtainable. This leads to

the second problem: the lack of a placebo effect trial. More research on the placebo implies, from a Clinico-empirical position, that the empirical substantiation of the placebo effect is precise and reproducible. This is not the case. The placebo effect is a kind of medical uncertainty relation. This "principle of placebo effect immeasurability" is very difficult for the Clinico-empirical position to handle. It is the scientific bench-mark of that position that the subject matter on which it focuses is measurable. Though generally the implication of the placebo effect on the Clinico-empirical position is a verification of the usefulness of its central concepts, the principle of placebo effect immeasurability sticks out, and makes the placebo effect if not a provocation, then a puzzle.

Placebo and the Scientific Medical Model

What is the implication of the placebo effect on the scientific model as such? In the beginning of the introduction I described the placebo effect as " a provocation and a puzzle to the present way of conceptualising medicine". This conclusion elaborates on that sentence. The placebo effect is a provocation to the Bio-mechanical position, but a puzzle to the Clinico-empirical position. There exists a general tension between the two positions of the scientific model, but with regard to the placebo effect the difference is polarised. The Bio-mechanical position cannot incorporate the placebo effect, but the Clinico-empirical position can. In that sense I do not regard the implication of the placebo effect to be a refutation of scientific medicine in general. The implication of the placebo effect on the scientific medical model is that the tension between the two position is intensified.

Chapter six:

Placebo and Hermeneutics

Humanities and medicine

Most lay men would classify medicine as a science, but as I mentioned earlier in chapter three, medicine has a much broader field than, for example, physics. Beside applied scientific and craftsmanship aspects medicine has an important humanistic dimension, as the whole discipline of medical philosophy illustrates. The results of scientific medicine are impressive; however, science cannot explain feelings and notions like: life crises, grief, angst, despair, sorrow etc. Most of us have experienced them, but what makes them of special interest to medicine is that they are closely linked with moments of troubles when one calls for a doctor - when one's every-day life is ruptured by threats of serious disease and death.

The placebo effect is in a scientific context most precisely described as an empirical phenomenon and as a part of clinical research methodology. However, the causal mechanisms initiating the placebo effect are better accounted for by a humanistic approach. How an individual patient reacts to the symbolic components of the clinical setting and the psychological interaction with the physician is more comprehensively described in a humanistic context. Framing the discussion about the scientific and humanistic element in medicine is a strict dualistic conception that science "cures" and humanities "cares". In the coming chapters I will address this dualism. At present I will give a sketch of a humanistic "model" of medicine. The sketch is not very detailed because my prime intention is not to develop an alternative humanistic medical model to the scientific one, but partly to contrast the scientific medical model, and partly to elaborate what I call the "the placebogenic complex" hypothesis. At the end of the chapter I hope it is clear that the placebo effect is a phenomenon that simultaneously is a key concept in clinical science and irreducibly mental.

Hermeneutics

I will approach the humanistic aspect of medicine in a broad hermeneutical tradition. The hermeneutical tradition encircles a great part of this century's continental philosophy and contains numerous complex philosophical discussions that will fall outside the scope of this work. I do not try to discus medicine and the hermeneutical philosophy as such, but intend to sketch an hermeneutical conception of the notions of causality, disease and therapy. One way of explaining the term hermeneutic is to contrast

it with science. Without being too superficial one can say that science is concerned with objective facts where hermeneutic concern itself with subjective meaning. The goal of science is "truth", or a "factual description". The goal of hermeneutics is to "understand" the fundamental conditions of being a subjective person. Its method is based on "interpretation". "Hermeneutic" was originally a term used for the method of interpreting the bible and the old Greek literature, texts that were looked upon as containing a special knowledge. It was transformed by Schleiermacher from its original narrow theological and Hellenistic scope to a method of broad textual interpretation. Dilthey again broadened the term to mean the general method of humanities, contrasted to natural science.

Causes and reasons

The notion of a cause is from a hermeneutical point of view not interesting. Causes exist, no denial about that, but from the perspective of the individual it would be odd saying: "I was caused to buy an ice-cream", or "The cause that made me wait two hours was that I had promised him to do so". A person is probably caused to do many things, one sleeps when tired and eat when hungry: is a part of a biological causal field. However, the notion of *reason* fits better with the experiences of the individual. We all have the feeling that we generally act freely. What makes John go to bed precisely then and there is not some objective "cause", but his decision, based on his subjective reasons for doing so. The value system and other factors effecting the decision of a person are relative to time, place and person, but the experience that we have

reasons for acting is part of being a human being. When I choose to stay at home today this is neither a random nor a determined event. I choose to do so, because I had a meaningful reason for doing so. Reasons can be seen as the cement of the person, as causes are the "cement of the universe"[86].

Meaningless illness

A hermeneutical approach to the concept of disease would focus on the patient's subjective perception of his disease, the illness. There are many aspects of importance with regard to the patient's illness, but for the present purpose I will restrain myself to look at the aspect of freedom limitation. A disease can be seen as nature taking over, as invading the intimate sphere of your body. The "silence of the organs"[87] ends and it becomes painfully clear that though free in the sense that John can choose when to go to bed, the freedom is limited, he cannot choose never to sleep. A disease is a process were the range of freedom of action is being limited. Being ill with the flu' I am free to choose between going to bed or drinking tea with honey, but I am unable to run the 15 km I use to. M.S. Konrad[88] states that "all illness represents a state of diminished autonomy". Without getting into a discussion of the notion of autonomy in medical ethics, I see his statement as emphasizing this narrowing of the scope of freedom. The disease behaviour initiated

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86 Mackie referrs to Hume in an introductory quotation in "The Cement of the Universe". Clarendon Press. Oxford 1974: p. v

87 Georges Canguilhem quoting René Leriche in "The Normal and the Pathological". Zone books. New York 1989: p.91.

88 Konrad, MS. A defense of medical paternalism: maximising medical autonomy. The Journal of Medical Ethics 1989;9:38-44.

partly by the patient and partly by the family reflect the changed situation. Tough masculine men incorporate the sick-role and have the opportunity to behave like children. The family accepts the helplessness and egoistic behaviour: "he is sick". The situation is well known and everybody play their roles, until normality is restored some days later days. The situation worsens severely if it is not a question of a banal flu', but a prolonged serious disease potentially fatal, chronic or invalidating. The question of the meaning of the illness becomes of paramount importance to the patient and his relative. Fundamental notions as self respect and personal integrity are threatened: the meaning of life and death is suddenly of concrete importance.

H. Brody examines in his book "Stories of sickness"[89] the use of narrative in medicine. It is a general analysis of stories told by patients (symptoms etc), to patients (explanations etc), among doctors (case stories) and almost every possible constellation one can think of. He sees stories, or the narrative, as the main coping strategy for patients with a "meaningless" disease. As he puts it *"suffering is produced, and alleviated, primarily by the meaning that one attaches to one's experience."*[90] The ability of patient to cope with the meaninglessness of a serious disease depends on the specific illness, the support of the social network, and the structure of the life story ruptured by the disease. The meaning of the sickness depends on how successfully the break in one's life story can be mended, made inevitable, reasonable or in any way

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89 Brody, H. Stories of Sickness. Yale University Press. New Haven and London 1987

90 Ibid: p. 5

meaningful. Williams and Wood[91] analyse in an interesting article the lay beliefs concerning the aetiology of chronic rheumatoid arthritis. Not surprisingly, the patient's conception of the causality of the disease was radically different from the general acknowledged scientific explanation. However, instead of pledging for more patient information, and regard the lay beliefs as "primitive", they analysed the structure and purpose of the patient's conception, and found that patient "errors" are not easily open to correction: they form part of a valued framework which helps patients to cope with the consequences of disease. The patient's beliefs form part of a narrative or "autobiographical" reconstruction sometimes conflicting with, but always interacting with, the public scientific explanation.

The doctor enhancing meaning

The etymology of the word "therapy"[92] is in accord with the hermeneutical conception of the term. "Therapy" can be traced back to the new Latin "therapaia", which again derives from the Greek noun "therapeia". Therapeia means: to serve or to attend, and is a nounification of the verb "therapeuin", meaning: an attendant or a servant. The hermeneutical concept of therapy takes for granted that the biological treatment of the patient is as good as possible, and then focuses on how the doctor more generally attends the patient. An attention that could imply enhancing the patient's

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91 Williams, GH & Wood, PHN. Common-Sense Beliefs about illness: A Mediating Role for the Doctor. The Lancet December 20/27 1986:1435-7

92 Churchill Medical Dictionary. Churchill Livingstone Inc. New York 1989: "Therapy"

coping of his disease. It is important that a physician acknowledges the importance of the narrative reconstruction as an essential part of the patient's coping. The role of the physician is limited, though. A person suffering from cancer will not, after talking to his doctor suddenly become happy and content, however, a mediating role for the doctor implies that the crises a serious disease initiates, is respected and addressed, and it implies, beside providing the facts of the situation, that the doctor can present new analogies, metaphors and explanations that will help the patient in the reconstruction of meaning. Doctors normally play a less important role than the family and close friends. If the physician is not aware of the possible schism between hermeneutical meaning and scientific truth he can, in the name of science, create unnecessary havoc in the narrative reconstruction.

A clinical example illustrates the conflict. A patient, having smoked for 40 years and recently successfully operated for a lung tumor, proudly tells his physician that, with great effort, he has quitted smoking. The scientific fact is that after 40 years of smoking the effect of stopping is very limited. How shall the physician react? A pure scientific approach would be to tell the patient to start smoking again as the great effort he refers is not worth the minimal decrease in cancer risk. A hermeneutically inspired approach would be to support the patient's effort in coping with the main cause to his self-inflicted disease. There are elements of punishment or expiation that have to be taken serious, and most important it gives the patient a feeling of active participation.

The Hypothesis of the Placebogenic Complex

It is difficult to describe specifically how the placebo effect and the narrative reconstruction of the patient interact, but I regard it as very plausible that the integrated value system and lay man model of medicine that both Brody and Williams address is paramount to the causal interaction leading to a placebo effect. Most attempts to give a detailed explanation of the mechanisms behind the placebo phenomenon have been unsuccessful. The conclusion most researchers agree on is that the placebo effect is a result of the general clinical setting and the doctor-patient relationship. This is a rather broad and general description by any standard, and a natural question to ask is what factors or relations are the most important. In the previous chapter I presented some common factors, for example patient anxiety. My intention now is to give an account of the structure of the dynamics between the clinical setting and the patient and the physician, and to elaborate this into a hypothesis regarding the placebogenic situation. I refer to a work by Adler and Hammet[93]. Their approach is not explicitly a part of the hermeneutical tradition, but I include it in this chapter because a central term of the model is identical with the hermeneutical term that I focus on: "meaning", and because Adler and Hammet's approach is in chord with the general hermeneutical way of thinking. My other source of inspiration is an article by Lévi-Strauss[94] called" The Sorcerer and his Magic".

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93 Adler, HM & Hammet, vBO. The Doctor-Patient Relationship Revisited- an analysis of the Placebo Effect. Annals of Internal Medicine 1973;78:595-8

94 Lévi-Strauss, C. The Sorcerer and his Magic, in Magic Witchcraft and Curing. University of Texas Press. Austin 1967: p. 35.

From a history of philosophy point of view it might seem strange to place Lévi-Strauss, one of the leading figures of structuralism, in a hermeneutical

Adler and Hammet assert that the placebo effect can by explained by the patient's relation to what they call "Group formation" and "System formation". They write:

" ... regardless of period or culture, those defined as patients-distressed or disabled-have always been helped by two aides of incalculable importance: participation in a shared cognitive system that made otherwise chaotic symptoms understandable and access to a relationship with a culturally sanctioned parental figure. We label these system formation and group formation respectively..." (author's emphasising)

System formation represents the world view, or the medical model. It is the tacit conceptualization's of health, disease and therapy. It is a *"comprehensive integrated coherent organisation of cognitive structures"* concerning life in general but also specifically how disease is to be explained. It is the medical "Weltanschaung" that most of us never verbalise explicitly, but nonetheless is necessary to make things "hang together", to locate yourself as a person in relation to a disease. Group formation is not only the special relation to a doctor: the doctor-patient relationship, but also the patient's relation to his social network, his family and friends. The importance of the social dimension is stressed in the article: *"In the beginning was not the word but the group."* They relate any

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context. However,the use of hermeneutics in this thesis and in medical philosophy generally is a fairly broad one, with no interest in distinguishing sharply between a phenomenological-hermeneutical and a structuralistic approach. Compared to medical science Lévi-Strauss and hermenutics are relatives that can be treated under the same heading.

therapeutic potential from group formation to a reactivation of the dyadic bond, the original mother-child relation, and conclude:

"It is suggested that these two factors -group formation and system formation- are as essential to psychic functioning as nourishment is to physical functioning, are the basic factors composing what is subjectively experienced as a feeling of "meaning", are invariable used in all successful interpersonal therapies, and are the necessary and sufficient components of the placebo effect."

Though I am not at ease with their use of the terms "necessary and sufficient conditions", or their postulating that a dyadic bond is reactivated, I think their general approach is interesting and fruitful.

Lévi-Strauss writes in a totally different context. His intention is to describe the dynamics between the Shaman and his patients, and he does not even mention the notion of placebo in his article. However, the structure of the dynamics he describes is very close to one developed by Adler and Hammet. Lévi-Strauss summarises his conclusion in the concept of "the shamanistic complex". The shamanistic complex is described as follows:

"... (the shaman) was fully convinced of two things-first, that pathological conditions have a cause which may be discovered and second, that a system of interpretation in which personal inventiveness is important, structures the phases of illness, from the diagnosis to the cure. This fabulation of a reality unknown in itself-a fabulation consisting of procedures and representations-is

founded on a threefold experience: first that of the shaman himself who ... undergoes specific states of psychsomatic nature; second that of the sick person, who may or may not experience an improvement of his condition; and finally, that of the public, who also participate in the cure experiencing an enthusiasm and an intellectual and emotional satisfaction which produce collective support, which in turn inaugurates a new cycle. These three elements of what we may call the"shamanistic complex" cannot be separated."
(authors emphasising)

One difference that comes to mind when comparing Lévi-Strauss´ term with modern western medicine is the role of individuality. The shaman often practises his craft in public. The fellow tribesmen watched and were actively engaged in the healing process. A modern doctor-patient relation is regarded as private. The most important axis is the one between doctor and patient; the individuality is even embodied through the promise of secrecy of the Hippocratic Oath[95]. However, this ideal of the doctor-patient relation reflects the praxis of a family physician, and is not in chord with the reality of most patients. In a hospital nurses and other patients create a public. The family and close friends is also a part of the modern public. A serious disease in every family creates an emergency situation, and the focus of the group is on the sick individual, in that sense a kind of public is created. The notion of publicity here aimed at has little to do with a political interpretation, as in the call for a free public press. It is meant as a

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95 See note 71 "The Oath": p 67.

theatrical notion, stressing the importance of a third person, an audience. A related difference between modern situation and the shamanistic complex, is the cultural heterogeneity of modern life. A tribe is culturally homogeneous in a way which makes a modern city seem totally chaotic. A parallel aspect of "the public" is the cultural meaning embodied in the term. The public does not only encompass relatives and friends, but also people who share some basic way of relating disease to the rest of the world, who share a medical model. "The public" is a term that in an anthropological situation is precise. However, I assert that in a medical context there are at least two aspects, one theatrical: the public as the audience, and one cultural: the public as the collective notions controlling and describing disease. In a modern setting the last version of the term is more important. The cultural-institutional basis of the doctor-patient relation is in medical terminology known as "the clinical setting".

My hypothesis is that a placebo response is generated through a modified version of the shamanistic complex. In a dialectical or cyclical way the doctor, the patient and the clinical setting interact. The specific nature of this dynamic is probably far more complicated than Lévi-Strauss indicates when indicating it as a necessary condition that the interaction *"is intellectually and emotionally satisfying"*, and based on the public *"experiencing an enthusiasm."* Instead, I think one has to regard the placebo complex as a highly complicated communicative process where the patient's individuality, the doctor's skills and the clinical setting in general support or accelerate a conception in the patient, but also in the

family and close friends, that what is being done fulfil their expectations of how a doctor and a patient should behave.
Both the meaning model and the shamanistic complex describe a triangular relation: a patient, a doctor and the cultural-institutional setting of their meeting. Both stress the dynamics in the relation as crucial. Both stress the importance of the group, and the paternal status of the healer. The "system formation" is synonymous with the "clinical setting", and the "group formation" is in the placebogenic complex split in "the doctor" and the social network aspect of the clinical setting.

A detailed account of the specific elements in the patient, in the doctor and in the clinical setting that initiate a placebo effect is difficult in itself, and also not within the scope of this thesis. What is important, though, is that the concept of Placebogenic complex anchors the placebo effect in a cultural-humanistic frame. At the moment it is not with any reasonable level of certainty and detail possible to define what factors, for example in the behaviour of the physician, that influence the placebo effect, but it is certain that the behaviour has cultural and symbolic implications. The placebo effect is a general therapeutical phenomenon that is initiated through the interaction between physician and patient in a way that transforms medical humanities from a pure academical to a therapeutical level. The placebogenic complex emphasises the dual character of the placebo effect: it is mediated through the patient's mental interpretation of his clinical situation, thus being a hermeneutical phenomenon, but at the same time, it is an integrated and inevitable concept in clinical science. The dualism

between science and humanistic or more specifically between mind and body is one of the aspects I focus on in the next two chapters.

Chapter seven:

The placebo effect and the Mind-Body problem

During the previous chapters I have avoided focusing on a problem imbedded most explicitly in the Bio-mechanical model, but wich, as well, implicitly, lies in the contrasting, if not conflicting, ways the Clinico-empirical and the hermeneutical positions interpret disease. I think of the problematic relation betwen the psyche and the soma, the body and the mind. As I have approached the placebo effect medical science and hermeneutics incorporate a conflicting concept of the nature of man. In philosophy it has been a predicament for many years how man at the same time is a part of nature and has a mind. The question is known as the mind-body problem. The contrast between the humanistic and scientific aspect of medicine, and the different status the psychological causes have in the two scientific positions reflect this fundamental metaphysical predicament. The former four chapters contained analyses of the epistemological implications of the placebo effect on scientific medicine. The following chapter contains an analysis of the practical medical distinction of body and mind, and the implication of the placebo effect on the mind-body problem.

Some mental categories

Before going on to discuss the competing positions of theory of mind, monism and dualism, it would be useful to categorise the different experiences we call mental. The mind has been divided in many different ways. Plato divides it in three: reason, spirit and desire and correlates it to the three classes in the ideal society in The republic: the philosopher rulers, the auxiliaries and the workers. Freud much later divides the mind into the super-ego, the ego and the id. A generally acknowledged division is between feelings and reason, and in theory of mind the status of feelings is sometimes debated. There is a long tradition in philosophy claiming that reason, or intelligence, is superior to feelings. Descartes even regarded feelings as not belonging to his concept of mind, res cogitans. Of course it is an impossible task exhaustively and exclusively to name the elements of the mind, the categories one distinguishes will often overlap considerable and the richness of the mental phenomena implies that some aspects always will be overlooked. The selection of mental categories reflects the intention of the analysis in which they are to be used, the present work inclusive. However, I hope that the categories I use are intuitively acceptable beside being normal philosophical terminology.

In the present context the mental categories I refer to are "sensations", "intentional states" and "subjective states". Pain is a mental phenomenon; so is solving a mathematical problem, and also the subjective valuation of the program of a political party. The first is a *"sensation"* or *"phenomenological state"*, often corresponding to an exterior influence, but not in the case of, for example, hallucinations. The second category is *"intentional states"*. Intentional states are the goal-directed features of the mind. We do

not just think, we think of something, there is a focus, or a purpose, in many mental actions. Whether we solve a mathematical problem, think of tomorrow's agenda, or fantasizes on the existence of unicorns, all are examples of intentional states. The third category could be called the *"subjective states"*. Subjectivism, or the particular point of view of the individual, is an important part of the mental landscape.

A hermeneuticel approach focuses on the subjective character of experience. However, also analytical philosophers, like Thomas Nagel, stresses the subjectivity of experience. In his essay "What is it like to be a bat"[96], he states: "It is difficult to understand what could be meant by the objective character of an experience, apart from that particular point of view from which its subject apprehends it. After all, what would be left of what it was to be a bat if one removed the viewpoint of the bat." Intentionality is sometimes meant to include the subjectivity of experience, but I think it is valuable distinguish the two terms. Intentionality includes in its weakest teleological form many natural events, for example the water of the river moving teleologically to the ocean, or the thermo-stat that perceives changes in the temperature, reacts teleologically and counters the change. Both are examples that, in the weak sense, are intentional. Intentional states in a more restricted form I call "subjective states" and do not include the teleological character of many non-conscious natural events, but presupposes an intending subject, a conscious person.

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96 Nagel, T. What is it Like to Be a Bat? Philosophical Review 1974; 4 LXXXIII:435-450

A modern dispute, that I will comment on in this chapter, concerns the status of the intentional states. The materialists will generally focus on intelligence as the paradigmatic intentional state, and make analogies to pocket calculators and computers. The critiques of the materialists will insist on the strong form of intentionalism, and regard the subjectivity of experience as the most important mental feature.

Dualism and Descartes

The idea that a person is a union of something corporeal and something spiritual, body and soul, is almost universal. The notion of the soul in contrast to the body is old, and present, for example in the works of Plato. In "The Republic" the soal is described as "immortal", and "deformed by the association to the body..."[97] The relation between the body and the soul, however, is very different in different cultures. In Japan, for example, the relation between soul and body is of a more integrated nature than in Europe. Sakai[98] regards this as partly expressed in the fact that, as one of the few industrialised countries, Japan does not recognise the brain death criteria.

In Western philosophy the discussion of the mind-body relation owes most of its basic concepts and problems to the strong dualism formulated by René Descartes in his "Meditationes de Prima

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97 Plato. The Republic: 611 c.

98 Sakai, Akio. Biomedical Interventions and the Japanese View of life and Death.

Philosophia" from 1641. Descartes radicalises in the light of Galileo and the new natural sciences the distinction between body and soul into what has become known as Cartesian Dualism. He discerns two fundamental entities: res extensa (matter), and res cogito (mind). Res extensa is physical matter, all that has extension, including the body. The body exists in time and space. It is subject to the mechanical laws governing all other lumps of matter, and can be inspected by external observers whose access to it is not direct and privileged, but must be guided via scientific method. The knowledge of one's own body is in principle uncertain, as it is logically possible to doubt its existence. Res extensa obeys the causal rules of nature. Res cogito is a radically different entity. It has no extension, is not a physical body. It exists in time but not in space. The mind is not observable by a third part. However, the private and internal character of my mind makes my access to it privileged. It is not logically possible to doubt the existence of one's mental activity, in so far as doubting is, in itself, a mental activity. As the mind is not a part of nature it is not subjected to determinism. Res cogito does not obey the causal rules of nature.

Descartes' problem, and the problem of all dualistic descriptions of a person, is to explain how two so fundamentally different entities can interact. When one deliberately lifts an arm, the dualists are in difficulties explaining how and where something non-spatial transforms into something spatial, how and where the mind (solely temporal and not subjected to causality), interacts with the body (spatio-temporal and subjected to causality). Descartes did not have any satisfactory answer to that question. His suggestion that the interaction took place in the pineal gland was not very helpful. In a

letter to the German Princess Elisabeth, Descartes states that he cannot account for the interaction, but only observes the evident fact that it takes place[99].

Dualistic theories are often distinguished by referring to the character of the causal relation between mind and body. Descartes' dualism is an example of *interactionism*. He believed that the body causally could effect the mind and the mind could effect the body. However, the difficulty of describing the nature of this interaction has prompted other dualistic variants. *Parallelism* states that mental events causally can effect each other, and bodily events as well effect each other, but that there is no causal interaction between body and mind. The lack of empirical examples of a person being happy and relaxed while, for example his hand accidentally is being squeezed in a vice makes parallelism implausible. Finally *epi-phenomenalism* is the position that corporal events can causally effect other corporal events and mental events, but that mental events only are epiphenomenal in the sense that they cannot causally effect anything. Epiphenomenalism can account for the pain caused by the hand in the vice. However, other examples, like how I can command my hand to move, or the difficulty of explaining how a causal chain suddenly stops at a mental event, makes the theory difficult to defend.

Monism

99 Descartes René. Letter to Prices Elisabeth of Boemen, in "Oeuvres Philosophiques", volume three. Garnier Frères. Paris 1973: p. 123.

The dualistic position, strongly inspired by Descartes, has not been unchallenged. The monists do not accept that man consists of two so radically different metaphysical entities. Focusing on the unexplained nature of the interaction between the mind and the body, they reject the division itself. The monists can be divided in idealists, materialists and neutralists. The idealists try to reduce the body into some variant of mental abstraction: the body does not really exists, only the mind. This position is not defended by many today, but Bishop Berkeley was close to this approach. Another strategy is applied by the materialists who try to reduce mental experiences to material physical phenomena. They have no difficulty explaining the so-called interaction between "mind" and body as they see the mind as secondary. However, the problem of the materialists is to explain the complexity of mental phenomena satisfactorily: not only sensations but also intentional states and the subjectivity of experience. I will discus the most important materialistic positions later. A third strategy, sometimes referred as neutralistic, is to re-define "mental" and "bodily" as terms that both are reducible to some third substance or category. The difficulty with this approach is to make understandable the structure of this third category and its relation to mind and body. An example of a modern neutralistic theory is Strawson's so-called Person-theory.

The "official" theory

Gilbert Ryle is a philosopher whose influential book: "The Concept of Mind"[100] from 1949 changed the framework of the mind-body

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100 Ryle, G. The Concept of Mind. Penguin Books. London 1990 (first published 1949).

discussion. He strongly criticised the dualistic position of his time as "the official theory". The dualism criticised is the old Cartesian form, sometimes referred to as *substance dualism.* Res cogito is regarded as a form of "mind-stuff", a different category of substance than matter, but still a some kind of substance. In his energetic style Ryle describes substance dualism as "the dogma of the ghost in the machine":

"... minds are not merely ghosts harnessed in machines. Though the human body is an engine, it is not quite an ordinary engine, since some of its workings are governed by another machine inside it- this interior governor-engine being one of a very special sort. It is invisible, inaudible and has no size or weight. It cannot be taken to bits and the laws it obeys are not those known to ordinary engineers. Nothing is known how it governs the bodily engine."[101]

The aim of the book is twofold. On one hand Ryle wants to refute dualism as such, and on the other hand he wants to advocate a behaviouristic variant of materialism. His negative aim has been successful. Few philosophers today would support the variant of dualism he aims at. In the half a century that has passed since the publishing of "The Concept of Mind", the "official theory" has changed from a substance dualistic position to a materialistic. A dualistic theory still defended is a *property dualism.* Property dualists do not regard the mind as some different form of quasi-physical entity, but they conceive mental properties as fundamentally irreducible to any body event. Ryle's main critique

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101 Ibid: p. 21.

was aimed at substance dualism. Many materialists regard property dualism as substance dualism in disguise, vulnerable to the same line of criticism as substance dualism.

Overview of materialist theories

Ryle's positive attempt to solve the mind-body problem was based on a *behaviouristic* theory. In short behaviourism tries to describe mental phenomena as dispositions to behaviour. The term can be divided into methodological and logical behaviourism. The former is a research strategy in psychology aiming at correlating objective observable stimuli to behavioural outputs. *Logical behaviourism* is a more radical position, as it states that language about mental phenomena is only understandable if it can be referred to some behaviour, or a disposition to behave. Logical behaviourism is closely linked to logical positivism, and their ideal of meaning. The ideal description of both the logical positivists and the logical behaviourists is one that only refers to aspects that are observable by a third person. To be "in pain" is conceived as a term for a certain disposition to cry out, blow at your finger, run in circles etc. Referring to some internal un-observable entity as "the feeling of pain" is regarded as meaningless. The research program of the logical behaviourists could be described as an interpretation of the normal mental terms of the language into behavioural categories only referring to observable behaviour. Regardless of the fact that behaviour and mental states are closely linked, the program of the behaviourists did not succeed. One common sense objection is that they have left out some essential aspects of the mind. A person

having the sensation of pain will never accept the reduction of the feeling of pain to pain behaviour. When an super-actor on stage treads on a nail and is in pain he does not necessarily scream and blow on his finger, but that does not mean that he cannot feel the pain. A parallel point of critique is that behaviourism do not recognise that pain-as-such causes pain behaviour. This lack of causal connection runs counter to a strong intuition in most people that have suffered from pain. Phrased more generally, if beliefs and desires are to be defined in terms of behaviour, they cannot at the same time cause that behaviour. Even more difficult is it for the behaviourists to explain intentional states and the subjectivity of experience.

Type Identity theory or also called *central state materialism* does not focus on behaviour, but claims that what we call mental events are identical with a brain event. As a case of scientific discovery "the mind" turned out to be the central nervous system, analogous to the re-definition of "water" as H20 or "lightning" as electrical discharge. Pain event X, then, is identical to neurophysiological event Y. The theory is attractive to many with a scientific background, and focuses the debate on a modern formulation of the mind-body problem: the mind-brain problem. However attractive to scientists, the theory has some serious flaws.

There is little doubt that the the nervous system is the organ where mental events are initiated, but that is not the same as to state that they are identical. It was discovered by Babylonian astronomers that the morning star and the evening star were identical. However, the radical difference between the morning-evening star example

and the mind-body problem is that persons have, and stars have not, sensations, intentional states and a subjective experience. These features of the mind are not explained by the scientific neurophysiological description of the brain. These states are caused by, or are functions of neurophysiological events, but to state that they are identical is to use the phrase "identical" in a unconventional way. With reference to Laplace's law "identical" mean that they have all their properties in common. This seems just not true. Imagine neurophysiological event Y: the pressure of the vice effects a nerve sensory organ, which changes its membrane resistance to potassium and sodium ions: in a split second the potassium leaks out and the sodium leaks into the nerve cell, which propagates a series of nerve impulses towards the central nervous system. Imagine pain event X: the vice squeezes my hand and it hurts terribly. How can X and Y be identical? My subjective feeling of pain is caused by the vice and transformed into nervous signals, but my conception of the pain, my conscious being-in-pain is not *identical* with neurons firing. Event x is subjective, and event y is objective. The only way I can make sense out of this identity is to use a weaker identity criteria. In a weaker sense identity could mean having certain essential features in common. This weaker form of "identical" is used by the central state materialists. Mental events are regarded as "essentialy" identical to brain events. However, brain events and mental events are not identical unless you reduce the subjective quality of a mental event, unless you find them essentialy irrelevant. But then there is no ontological identity. The problem is that the subjective quality of experience is an essential property of many mental events. The reduction of the

mind to nothing more and nothing above the brain leaves out a proper explanation of the mental experiences.

A materialistic theory, that can be seen as a merging of both behaviourism and identity theory, is called *eliminative materialism.* Instead of trying to define mental phenomena in terms of behaviour, or claim its identity with neurophysiological events, eliminative materialism bluntly denies the real existence of mental phenomena. Instead they see them as linguistic rudiments from a pre-scientific time. The criticism that makes behaviourism and identity theory implausible does not in the same grade affect eliminative materialism. As "the mind" does not really exist, the problems of causal connection and identity criteria are neutral to the theory. It has to be taken seriously because it claims to be a radical reconstruction of our perception of "the mental". It is not, as behaviourism and identity theory, an explanation. An eliminitive materialist will emphasise that our language about, for example diseases, has changed as medicine has introduced more precise terms. We have stopped talking about demons and instead talk about bacterial infection. When our knowledge of mental events increase we will learn to use more precise scientific terms, "I am in pain" will be exchanged by the term "my C-fibres are firing"[102] While an objection could be that I cannot be wrong about my pain, incorrigibility does not exist with regard to the c-fibres. The eliminative materialists would reply that such an objection shows

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102 It is part of philosophical terminology to describe nerve cells that transmit pain impulses as "c-fibres". This is, however, not precise in neurophysiologal terms. The c-fibre axons are only one type of pain transmitting cells, others are, for example, A-delta fibres . The focus on fibres overlooks, as well, the importance of the type of nocireceptor initiating the pain signal.

how muddled up we are in the use of mental language. He would claim the situation is analogous to the physicist engaged in the phlogiston combustion theory opposing the existence of oxygen by saying "This sounds all right, but since there is no place for phlogiston, your theory must be wrong". The reconstruction of our language, meaning the elimination of mental terms, is a kind of philosophical linguistic revolution, similar to a scientific revolution.

An objection to eliminative materialism is to oppose the shift of mental phenomena from a ontological to a linguistic status. Mental states, like consciousness, are real because they cannot be reduced without reducing a fundamental feature of being human, the subjective experience of being a self. To say that one really never felt fear, love or pain runs counter to very strong intuitions. And if it is just a question of changing the name of the same entity, this seems to be unreasonable work, and is of little interest. The aim of the theory is not just to define black as white, but to eliminate the mental states. Again a materialistic theory cannot explain central mental phenomena.

Computer Functionalism is the fourth materialistic theory I want to focus on. Inspired by the research in artificial intelligence and computers the basic analogy is that the brain is the hardware or "wetware" and the mind a kind of software. The functionalists claim that the central nervous system has physical properties, but also properties that, at the same time, are causally linked to and functionally independent of neurophysiological events: mental properties. The causal connection between body and mind is built into this theory, and so is the irreducibility of the mind. The

function of solving the quadratic equation can independently be formulated in the software of a computer program, described in mathematical terms on a piece of paper and can be stored in the brain of a student. The same property, or function, is individually causally dependent on its physical "hardware" (silicon chips, paper and ink, brain cells) but functionally independent. The intentionality of some computer programs copy the intentionality of mental activity, for example solving a mathematical problem like calculating a quadratic equation. Functionalism is a sophisticated theory that on the surface seems to merge dualism and materialism. However, it has the similar flaws that most materialistic theories have. The subjective quality of consciousness is not addressed in functionalism. A computer may copy intentionality in a broad sense, but it has no consciousness and no individual meaning connected to its "intentional activity". The mind may have features in common with computer programs but that does not in itself make the mind a program. In a later part of this chapter I will focus on the problems regarding the mind's possible existence outside the brain, as well as on the hypothetical conscious computer.

Mind-body in medicine

Medicine is a sphere where the practical expression of the theoretical mind-body problem surfaces. The terminology in medicine, however, is different from philosophy. Where a philosopher says mind and body a doctor uses the synonymous terms: psyche and soma. When speaking of "diseases", without the

use of a prefix, what is tacitly meant are *somatic diseases*, disorders of the body, not caused by mental influence, and with no mental effects. An example is the fracture of a leg. However, when the mind's influence on a disease is evident the use of a prefix becomes urgent. *Psychic diseases*, as neurosis or obsessive disorders, are diseases of the mind. Psychiatry has always been the "enfant terrible" of medicine, and I will omit the complex discussions regarding its methodology and relation to psychology. What I want to point out here is that the sharp distinction between somatic medicine and psychiatry reflects an underlying dualistic perception of man. A further need for prefixes becomes evident when the bodily disease influence the mental capacity in a pathological way: *somato-psychic diseases* , as for example most neurological diseases. Probably the most well known term regarding the medical distinction of diseases in bodily and mental, is *psycho-somatic diseases*. It describes disorders that, at least partly, are mental in their causation, but affect the body: Ventricular ulcer is often pointed out as a psycho-somatic disease.

The dualism here expressed has a tendency toward both parallelism and epiphenomenalism. The parallelistic tendency becomes clear by the fact that diseases of an interactional nature are much more controversial than psychic diseases as such. Few find the notion of neurosis as problematic as for example the nervous component of Crohn's disease.The epiphenomenalistic tendency surfaces when one focuses on the different status given to somato-psychic compared to psychosomatic diseases. Somato-psychic, or in general neurological diseases do not cause nearly the same uneasiness among doctors as psycho-somatic diseases. Though

encompassing tendencies both to parallelism and epiphenomenalism the dualism expressed in medical terminology is basically interactionistic. It is describing a two way causal interaction between body and mind.

Somatic diseases are the hard core of medical praxis and science. Within the scientific model the objective observable body, without the irregular subjective influence of the mind, is the ground on which certainty and regularity can be achieved in medicine. Psycho-somatic diseases are from an Clinico-empirical position seen as peripheral cases where the mind has to be incorporated in the description of the disease. A bio-mechanical position would tend to bias toward epiphenomenalism, or not accept the real nature of mental phenomena. Though medical terminology expresses interactionistic dualism, the status of the terminology is restricted to an epistemological level. Few physicians, when asked about the true nature of this terminology, would accept it as expressing an ontological truth. Most physicians think within the scientific model. The majority of them are ontological monists, or to be more precise: materialists. The mind is seen as a function of the brain. Neurons that individually function at a simple on-off level will, when they are organised in a complex neuro-physiological network- like the brain, provide the basis for mental capacity. The terminology used to categorise diseases in mental or bodily is seen just as a heuristic device in so far as our present knowledge of the complexity of the brain is not sufficient for a better alternative. The medical mind-body relation can be described as an epistemological dualism and an ontological materialism. The epistemological dualism of medicine is fundamentally interactionistic, but incorporates tendencies

toward both parallelism and epiphenomenalism. In other terms it can be described as soft dualism sprayed on hard materialism.

At a practical clinical level this heterogeneity between the epistemological and ontological level is not necessarily problematic. Pragmatically the medical profession is more concerned with potential therapy than theoretical consensus. There may be good reasons for the mind-body problem being primarily a theoretical philosophical problem. The practical implications of theoretical disputes that have no conclusion is often therapeutic doubt and frustration. From a philosophical point of view, however, it does not change the ontological problem of relating mind and brain that the medical profession operates with contrasting epistemological and ontological levels. The ontological position is the fundamental one, and medicine and philosophy share a general materialistic consensus. The interesting question with regard to placebo is then whether the placebo effect can be satisfactorily explained within a materialistic theory.

Placebo and materialism

How would a materialist account for the placebo phenomenon? In discussing this question one must distinguish between research strategies, and philosophical positions. Some work has been done in relating the placebo effect to both bio-mechanical functions and behaviouristic psychology. As I have pointed out earlier this has been partly successful. The analgesic effect of the placebo response have been linked with internal opoid secretion, and some aspects of the placebo effect has been explained as conditioning. However, this

section is about the philosophical materialistic interpretation of the placebo. One thing is scientifically to try to uncover bits and pieces of the biological causal relations of the placebo effect. Something radically different is to give the phenomenon as such a framework, that is philosophically to give a meaningful materialistic account of how a pharmacological inert pill can be medically effective.

The first materialistic theory I will focus on is logical behaviourism. One basic assertion of the logical behaviouristic position is that every statement about psychological or mental states can be re-formulated in terms of observable behaviour. The "mind" is a black box model and the only meaningful language about it must refer to observable behaviour. Can the placebo effect be re-formulated in behaviouristic terms? A necessary condition for the placebo effect is that the patient is conscious and that he believes in the clinical setting. Belief states are re-formulated as dispositions to behave. "I believe in the clinical setting" is then translated into: "I am disposed to follow instructions by the person in charge, to endure pain inflicted by diagnostical procedures" and if asked about being in a clinical setting the answer will be affirmative. However, this translation is if not incorrect then incomplete. True that most patients being in a clinical setting behave according to their situation. However, there are situations where a patient behaves as described without believing in the clinical setting. I do not only think of an actor playing a trick, but also of patients who do not believe in the treatment they get, but continue because they believe in authority, or because their family make them. Similarly, one can truly believe in the clinical setting, but fear of the uncomfort and pain connected to a cure make you act differently. A

reformulation of the translation could make "disposed" include "having no desire to act " or "understanding the significance of the situation". However, then mental terms like "desire" and "understanding" have crept in, which defuse the intention of the behaviourist. The behaviourist can try again to reformulate his "translation", but at least Putnam[103] regard this process as in vain. He sees this as a general feature of logical behaviourism: no psychological terms can be characterized adequately in such a way as to eliminate all psychological terms from the explanation. The placebo phenomenon being a psychological term, cannot be adequately explained by logical behaviourism.

Identity theory and eliminative materialism are in their relation to the placebo effect so close that I will discuss them under the same paragraph. They would both have difficulty explaining the placebo phenomenon. They would emphasise that what really happens are neurophysiological events, triggered by complex cerebral integration of sensory stimuli. The behaviouristic black box is opened op and filled with neurons. However, the lack of detailed understanding of the neurophysiological events and the triggering mean that the account of the placebo effect is meagre. An alternative strategy would be to regard the placebo effect as a regression to a pre-scientific language, that from a heuristic point of view is understandable and epistemologically convenient, but ontologically unacceptable. In other words, the placebo effect does not exist, it is just a convenient nominal term for biological processes we yet do not understand. The answer to such a

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103 Putnam, H. Robots: Machines or Artificially Created Life? Journal of Philosophy 1961;668-91.

reduction would be that the nominal character is something placebo share with other central medical scientific notions, like "disease". The reduction of placebo cannot be made without reducing the medical scientific model to the classical bio-mechanical position. By eliminating the mental phenomena "placebo effect" the eliminative materialist in fact clashes with his own scientific foundation. Eliminative materialism and identity theory cannot give a satisfactorily account for the placebo effect.

A functionalist would conceive the placebo phenomenon differently. From a functionalist point of view any mental feature causally effecting the body is equivalent to the "mental software" causally effecting the "bodily hardware". There is nothing strange about this, the analogy to a printer or other hardware functions comes to mind. Though possibly puzzled about the existence of a kind of mental "placebo-program" it is principally conceivable. However, the necessary condition of the placebo effect: consciousness, is difficult to relate to a computer analogy. A computer does not believe anything and is not conscious about anything. A functionalist could argue that consciousness and believe (for example in a clinical setting), is a function of a "consciousness program" of which the "placebo program" is a sub-program, but this tells us little. It would mean going far into cognitive science and neurological network theory to sketch what kind of "program" consciousness or the placebo effect is a function of. This exploration is in nature not philosophical but a part of what some call cognitive science. From a philosophical point of view the framework of the functionalists' account of the placebo effect cannot be refuted as easily as the other materialistic theory, but the lack of coherent clarification of

what a "consciousness program" means make the functionalistic explanation of the placebo effect unsubstantiated.

Placebo and dualism

The outlined materialistic positions cannot satisfactorily account for the placebo effect. In this section I will focus on the competing dualistic attempts to clarify the phenomenon. However, before I do so I think it would be useful to categorise different types of medically relevant mind-body interactions.

There are at least three levels of interactions between the mind and the body: the first level could be called *psycho-physiological* and is exemplified by the bodily changes relatable to every day mental events: anger is associated with paleness, when one feels shame one blushes and the heart beats faster if one is scared. The second level could be called *psycho-pathogenic* and describes when the mind is a non-redundant part of pathogenic causal field, promting a psycho-somatic disease. Beside ulcer I could mention several dermatological disorders, as for example psoriasis. The third level could be called *psycho-therapeutical*, and aims at describing the situation when the mind is a non-redundant part of a causal therapeutical field. The cures of hysteric functional disorders by psychotherapy in the beginning of this century is an example. However, today the functional disorders are very rare, and the therapeutical potential of psychotherapy, following a parallelistic trend, is directed towards psychic disorders as for example neuroses.

A dualist regards the placebo effect as a re-emphasis of this third level relation. The mind is not only causally effective with regard to ordinary psycho-physiological events, or potentially dangerous psycho-pathological events. The mind is, in certain situations, capable of influencing disease: the placebo effect is an important example of the curing psycho-therapeutical interaction between mind and body. The concept of mind in medicine has been put under pressure by the bio-mechanical position. The placebo effect re-emphasises the importance of mind. It is not just a ghost in the machine, but a ghost that heals sick people. The parallelistic and epiphenomenalistic tendencies in the practical medical dualism cannot explain the placebo effect. Not only does the mind effect the body, it interacts causally and therapeutically. Interactionistic dualism has no difficulty explaining the placebo effect. The placebo effect is an example of a special therapeutical causal relation between the mind and the body.

Implications of the placebo effect on the mind-body problem

At this moment it seems as if the placebo effect illustrates the predicament of the mind-body problem. The shared medical and philosophical position is scientific and seem incongruent with dualism. Mental phenomena, as for example the subjective quality of experience, however, seem unexplainable within a materialistic theory. An alternative name for the mind-body problem could be the mind-body paradox. Placebo is no different from other phenomena that have essentially mental properties: it is well explained by an interactionistic dualistic theory, but not easily

comprehended by a materialistic theory. The difference, though, between the placebo phenomenon and, for example, a mental property as self reflection, is that placebo is an integrated part of the scientific model of medicine. It cannot be eliminated from clinical science without thwarting what in the last half century has been regarded as the proper scientific method of clinical investigation. The placebo effect is an example of a mental entity that thwarts any materialistic attempts of reduction, but for a different reason from most mental phenomena. Not only is it difficult for a materialistic theory to explain the nature of the placebo effect, in this way placebo is similar to many mental properties. But the placebo effect is, at the same time, part of the scientific model and a mental phenomenon, it cannot be reduced without at the same time reducing the scientific model to a bio-mechanical position. This position represents a classical, in some sense obsolete, perception of medical science. The implications of the placebo effect on the mind-body problem is that it emphasises its true problematic or paradoxical nature. By being a phenomenon simultaneously scientific and mental its irreducabillity has to be accepted even from a materialistic point of view.

Chapter eight:

Biological naturalism and the placebo effect

What is redder, the rose or the communist?

When a philosophical question seems unsolvable, one possible explanation is that the question is asked in a wrong way. "What is redder, the rose or the communist?" is an example of a question where the syntactic logic is invalid. Few problems in philosophy are as simple as the example above, where the word "red" is used confusedly both as a colour and as a metaphor for a political position. However, what I want to illustrate is that a philosophical "Gordian knot" sometimes is tied up with the fundamental assumptions implemented in the way the problem is formulated.

René Descartes formulated the mind-body problem, but beside being a great philosopher he was also a catholic and a scientist. His strong dualism provided each area their subject matter. Religion and philosophy was concerned with the mind. A mind that thus was freed from the apparent determinism of nature. The exorcism of the mind from the subject-matter of science, on the other hand, enabled scientists to focus on phenomena that were objective and measurable. However, as a foundation to this strong cleavage lies the assumption that the mind cannot be irreducibly mental and at the same time part of nature. The assumption is opposed by the American philosopher John Searle in his book "The Rediscovery of Mind"[104]: "Dualists treat the irreducibility of consciousness as incontrovertible proof of the truth of dualism. Materialists insist that consciousness must be reducible to material reality, and the price of denying the reducibility of consciousness would be the abandonment of our overall scientific world view." The intention in "The Rediscovery of Mind" is to show that the disjunctive ontology of something being *either* mind *or* nature is a heritage from Descartes that has to be confronted. The mind is neither a ghost, nor chemistry, but a unique part of nature that is irreducibly mental.

I will in the following chapter present Searle's theory of mind: biological naturalism, and discuss whether he, as he claims, solves the mind-body problem and thus provides a congruent and defensible philosophical basis for the understanding of the placebo effect.

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104 Searle, JR. The Rediscovery of Mind. A Bradford Book, The MIT Press. Cambridge, Massachusetts 1992: p. 116

The mind is part of nature

In the previous chapters I described the scientific model of medicine. The strength of this model is not only that it gives an ontological description of the nature of diseases and that this description epistemologically is under empirical control. Possibly its greatest advantage is that it harmonises with other scientific models as for example the atomic theory of matter, and the evolutionary theory of biology. It is an integrated part of a highly complex but nonetheless relatively coherent scientific world view. The expanding character of this world view is expressed by a proword attributed to Galileo: "measure everything, and make measurable what cannot be measured". The expansion of the subject matter of science has continued in irregular leaps since Galileo's formulation of his laws of motions. It has steadily moved closer to the scientific basis for the mind itself. The fields of molecular biology, genetics, and neurophysiology are examples of scientific fields having the central nervous system, or the brain, on the agenda. Today it would not be controversial to state that this research tells us something important about the the mind, implying that the working of the brain is the basis of our metal capacity.

How can the relation between the mind and the brain be perceived from a scientific point of view? If one regards the theories of evolution and neuroscience as the most relevant scientific theories concerning man and the brain, the following outline would not surprise. During the evolution of animals, certain cells have specialised in the transmission of signals: nerve cells. In the beginning this transmission was comparable to simple reflexes.

During the evolutionary process, however, the number and complexity of the organisation of the nerve cells increased and "central nervous systems" developed. What constitutes the greatest difference between the species "homo sapiens" and its closest evolutionary relatives: the big apes, is the organisation and size of the central nervous system, primarily the cortex of the brain. The extremely complex organisation of the neural networks in the human brain is at the same time vulnerable to general chemical manipulation, as for example during alcohol intake, and capable of very specific tasks as intelligent behaviour, linguistic ability and fine discrimination sense. The mental properties constituting the mind are caused by the organisation of the brain, by the complex interaction of nerve signals and neurotransmitters. Searle describes the central mental property of consciousness as: *"a biological feature of human and certain animal brains. It is caused by neurobiological processes and is as much a part of natural biological order as any other biological features such as photosynthesis, digestion, or mitosis."*[105]

The importance of a correspondence with the biological knowledge of the human organism and its place in nature is expressed by the name Searle has given to his theory: "Biological naturalism". Naturalism is a term giving emphasis on nature as we describe it, consisting of atoms, molecules, forces and electrical fields. There are no demons or ghosts in nature. The term "biological" emphasises the special place living organisms have in nature. One of the peculiar things about living organisms of a certain complexity such as

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105 See note 104: p. 90

humans, is that we have minds. The general scientific framework of biological naturalism places it close to the materialistic theories, for example, identity theory, but I must stress the difference. Where identity theory states that mental events are identical to brain events, biological naturalism states that mental events are functions, or effects of brain events. From this perspective the mind is not a ghost in a biological machine, it is a causal effect or a function of the machine.

The mind is irreducible

Many theories of mind focus on intelligence, intentionality, memory or sensations but there are few that emphasize *consciousness*. Searle explains this by stating that consciousness has a special status in the mind. It is the fundamental capacity of the mind, the capacity that makes the mind truly mental. Any materialistic account of the mind will try to avoid consciousness. Any comprehensive theory of mind must concentrate on it. Searle says: *"In one way or another all other mental notions, such as intentionality, subjectivity, mental causation, intelligence, can only fully be understood as mental by their relations to consciousness."*[106]

He does not give a formal definition of what is meant by the term, but instead offers a broad description. He regards consciousness as a reho-stat: it is an on-off system, that once on, has a spectrum of possible intensities. Either one is conscious, as when awake, or one

106 Ibid: p. 84

is not, as when asleep. Its on-off aspect is the necessary condition for all other mental features of the mind. Intelligence, for example, is often seen as the true mental activity; however, intelligent behaviour would not be regarded as intelligent if the person behaving was unconscious. A computer may have a powerful processing capacity, but no one would use "intelligent" other than as a metaphor to describe a computer, even if it solves the same questions as a person doing an IQ test. For anything to be mental it must first be conscious. Being conscious, however, one can be less conscious as when one has just woken, or more conscious as when making love.

The positive structure of consciousness, the features that transcends the simple on-off nature are difficult to define. However, Searle asserts that the structure of consciousness can be described in terms of a number of features.[107] Partly because of space restrictions and partly because that part of his discussion has more to do with psychology than the mind-body problem as such, there is little reason for going into the detailed description of these features of consciousness. However, one of them is intentionality, a feature that I discused in the previous chapter. Another feature is that my consciousness has a centre and a periphery. At the moment I am very conscious of writing on a PC (the centre) and less conscious of the pressure of the shirt against my skin (the periphery). Subjectivity is possibly the most important feature of consciousness. By the subjective feature of consciousness is meant

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107 The most important, beside the ones I mention, are: temporality, sociality unity and familiarity. Searle does not discuss the temporal or the social aspect of consciousness in detail.

its point of view aspect: the fundamental experience that I am an individual existence, different from other persons. I will in the following discuss the distinction subject-object with regard to the mind more generally.

The terms "subjectivity" can have at least two meanings. Firstly, an emotive or discursive connotation. For example, when making statements whether fish and chips taste better than pizza, or whether the water is too cold to swim in or not, we call such statements subjective. A synonymous term is observer-dependent statements. There are no measurable, matter-of-fact relations that can settle such a dispute. The form of subjectivism here aimed at is called *epistemological subjectivism.* Another more radical meaning of the term is called *ontological subjectivism.* When I say "I have a pain in my foot" I am not expressing some kind of emotive discussable preference. The statement is real in the sense that it refers to a factual matter: it hurts, and secondly I am the only person capable of assessing the feeling of pain. There can be no way of discussing the matter if, or if not it hurts, one cannot be mistaken about the feeling of a pain. One can deceive, and say it hurts when it actually does not, but it is a matter of fact whether it hurts or not. The existence of a pain is a first-person existence. I, as an individual, have a special relation to my mental states[108]. The first-person existence is a general feature of consciousness. All my

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108 It is worth noting that this is not equivalent to saying we have the traditional dualistic claim of incorrigibility and of a special sense of introspection. They are not features that characterise consciousness, and are refuted by biological naturalism. What is stated is the humble fact that an individual by having a consciousness has a relation to his mental states that differs from his relation to other persons mental states. The complex other-mind problem is addressed by Searle, but will not we discussed in this thesis.

conscious forms of intentionality founding any information of the world independent from myself are from a special point of view. The world independent of me has no point of view, it is objective, but my access to it through my consciousness is always perspectival, always subjective in the ontological sense.

Epistemological objectivism means the unbiased reconstruction of the world. I use the phrase "reconstruction" because this level of objectivity is methodological and aware of the possible biases related to the subjectivity of the observer. It makes no claim of being the reality, but claims to be the best description of it. However, one can speak of *ontological objectivity* as well, meaning the world in itself, the real thing independent of any methodological discussion or uncertainty. What happens when we try to use the terms on the special biological feature called the mind? How can science with its ideal of epistemological and ontological objectivity observe mental properties that are ontologically subjective? Well, they can try an behaviouristic approach or an identity theory approach, but the result has not been convincing. The problem is that it is impossible to objectivise the subjectivism of consciousness without loosing an essential part of consciousness: its subjectivity. The scientific method, the idea of objective observation and the jettison of epistemological subjectivism is a relatively efficient and fruitful strategy when focusing on the part of the world that is ontologically objective. However, it is inefficient when it comes to accurately describing the mind: a part of the world that is ontologically subjective.

The recognition of the metaphysical status of ontological subjectivism is one of the main points of dispute in theory of mind, and has been so for many years. The discussion of subject-object is not new either, and can, for example, be found in the works of Kierkegaard[109]. Discussing the relation between a person's subjectivity and scientific objectivity he concludes, parallel to biological naturalism, that: *"The way of objective reflection leads to abstract thought, to mathematics ... and it leads away from the subject, whose existence or non-existence, from the objective point of view quite rightly, becomes infinitely indifferent."*

The traditional materialistic reply to the paradoxical objectivisation of the subject is to deny the subject an ontological status. In other words ontological subjectivism is reduced to epistemological and ontological objectivism. The following section will focus on the *reduction* of the mind. The discussion is problematic because authors use the term " reduction" in several different ways, and I have to clarify the terminology I want to use. One can at least speak of three main categories of reduction. Possible the most important one is the *ontological reduction*. Ontological reduction implies that a certain class of entities is nothing more than another kind of entity. A flash of lightning is nothing more than an electrical discharge, and a gene is nothing more than DNA.[110] A second category could be called *definitorical* or *epistemological reduction*. An example is

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109 Kierkegaard, S. Afsluttende Uvidenskabelig Efterskrift. Quoted in Wulff, HR. Philosophy of Medicine (2. ed). Blackwell Scientific Publications. Oxford 1990: p.132.

110 I use Searle's heuristic example, but am aware that a gen contains more than DNA, for example the different classes of histons. However the point of the argument is not affected by the fact that the redefinition refer to more than one entity.

the logical behaviouristic attempt to redefine mental terms in terms of behaviour. Implicit in this approach is that if the epistemological reduction is successful the entities referred to can be ontologically reduced as well. Finally the third main category is *causal reduction.* Causal reduction implies that one type of things can be fully explained by the causal power of a second class of things. The first type of things are then reduced to the first type. For example solidity is a feature of a physical object totally causally explicable by the nature of the atoms and molecules in the structure of the object.

What kind of reduction do the materialist aim at when claiming that mental properties are reducible to the brain? Well, there seems to be little doubt that they aim at ontological reduction, either directly (identity theory) or via epistemological reduction (behaviourism). However, their main argument is based on the scientific knowledge that mental properties are caused by brain events. The question of interest is then: does causal reduction imply ontological reduction? If one looks at the history of science for guidance it seems that it does. The colour red, for example, was once defined ostensively by pointing at a red object. The "real red" was then defined as what seemed red to "normal" observers under "normal" conditions. The discovery of the causal mechanisms underlying light: photon emission, wave-particle dualism etc, a redefinition was inevitable. Red can today be defined as a photon emission of 600 nm. The ontological reduction of red from the colour of a rose, to photon emission of 600 nm was complete.

The project of redefining colour to photon emission or heat to molecular movement was based on the jettison of the subject from scientific exploration. The observer-independent qualities is the true scientific subject matter. In the continuous expansion of the scientific project the methodological jettison of anything observer-dependent does not restrict itself to subjective notions like heat and colour, but aims at ontological subjectivism as such. The logic of the jettison of the subject from scientific pursuit requires us to distinguish between appearances and reality. Heat is the appearance whereas molecular movement is reality. Pragmatically there is no necessity in such an eliminative redefinition. As a subjective person I still feel hot while being in a sauna. Though as an intellectual game I may speculate about the thermodynamics of a sauna oven, what quickly occupies me the most is the subjective feeling of heat. The idealists would start from this point and not accept this reduction at all. However, there are few today that would claim that there is nothing more to reality than appearance. By focusing on causal connections in the physical reality around us we do achieve a better understanding, and perhaps more important a greater manipulative control over that reality. The pragmatic emphasis of the meaningfulness of the use of subjective terms in daily language is, however, an epistemological attempt to defuse the scientific objectivisation of the world. Every person speaking English uses the word "heat", even an eliminative materialist, but the materialist would give the term a restricted epistemological status.

The crucial problem for a biological naturalist is to show that the relation consciousness-brain is different from the relation heat-

molecular movement. One possible strategy is to ask what happens if one tries to distinguish between appearances and reality with respect to consciousness? It is difficult, not to say impossible, to do that. Once one tries, the mental disappears and one is trapped in the materialistic corner of not explaining the character of the mind. It seems that a crucial feature of consciousness is that reality and appearance merge, that the distinction so meaningful with regard to other natural phenomena is meaningless when used on consciousness. Searle describes it as follows: *"Indeed it is a general feature of such reductions* (from a subjective to an observer-independent term, A.H.) *that the phenomenon is defined in terms of the "reality" and not in terms of "appearance". But we can't make that sort of distinction for consciousness because consciousness consists in the appearances themselves. Where appearance is concerned we cannot make the appearance-reality distinction because the appearance is the reality.* "[111] Consciousness is a special part of nature where a causal reduction does not imply an ontological reduction. The ontological reduction of mind is impossible to conduct because consciousness, as the only part of nature we know of, has the status of ontological subjectivity. From this perspective the apparent paradox becomes logical: the mind is ontologically but not causally irreducible, and a part of nature.

The mind-body problem as a neurophysiological problem

[111] See note 104: p. 122

How does biological naturalism respond to the classical interaction problem between its two irreducible entities consciousness and neurophysiology? The apparently incomprehensible way the brain causes consciousness is a fascinating and highly problematic question, but is it necessarily a philosophical question? It has been regarded as such for several hundred years with little success. Is it not possible to reinterpret the question so it is part of a neurophysiological research program instead of a conceptual philosophical problem? There is nothing wrong with a dual approach, but I think it is important to note that historically there are many examples of problems that have for many years been regarded as philosophical and which at the end was solved by a scientific analysis. For example electromagnetism was a subject that prompted philosophical analyses of a Hegelian nature during the nineteenth century. Hans Christan Ørsted, the physicist that discovered that a magnetic field surrounds every electrical current, wrote a philosophical treatise called "Nature's Spirit" [112]. However, after Maxwell's equations few would regard electromagnetism as a relevant philosophical problem. Biological naturalism claims that the brain-consciousness relation is as incomprehensible today as subatomic physics before quantum mechanics or electromagnetism before Maxwell's equations. From this point of view Searle's "solution" of the mind-body problem is analogous to Popper's "solution" to the induction problem. Popper did not solve the induction problem; in a way he defused it by his falsificationist theory. From a philosophical point of view the mind-body problem could be said to be "defused" in the sense that it is expelled from

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[112] Ørsted, HC. AAnden i naturen (Nature's Spirit). Naturvidenskabelige Skrifter. København 1920.

the subject matter of philosophy. The way the classical body-mind problem is asked makes it impossible to answer. What is then left for philosophy? Is the mind-body problem one of the philosophical problems that is going to be solved by science? From Searle's point of view philosophy has little interest in the mind-body problem, but great interest in the mind and in consciousness. That the mind-body problem is a neurophysiological problem does not mean that philosophy of mind is neurophysiology, on the contrary, freed from the corset of the Cartesian framework, implicitly acknowledged by both dualists and materialists, the philosophy of consciousness can be explored. Apart from that, any success in the neurophysiological research project concerning how the brain cause consciousness, would probably be very interesting for theory of knowledge and philosophy of science and medicine. The mind-body problem is a philosophical pseudo-problem.

The Placebo effect and biological naturalism

Is biological naturalism a theory that, in contrast to the theories of mind previously discussed, presents a satisfactorily philosophical framework for the understanding of the placebo effect? Biological naturalism does not regard itself as a variant of interactionistic property dualism. However, as a matter of practical explanatorical capacity there is little difference between property dualism and biological naturalism. The later theory insist that there metaphysically both exists something irreducible mental (consciousness) and neurophysiology. The placebo effect is thus interpreted as a special capacity of the consciousness

therapeutically affecting the body. However, if the placebo effect is compared to other conscious actions, for example the lifting of an arm, there clearly is a difference. I can decide to lift my arm but I cannot decide to be cured by a placebo effect. Though founded on consciousness as a necessary condition the placebo effect is not subjected to volition. The placebo effect is a phenomenon that, though on the one hand, is resting on the on-off feature of consciousness, on the other hand, it is sliding into the unconscious. The placebo effect points out a problematic feature in biological naturalism: the relation between consciousness, unconsciousness and the mental.

A feature of consciousness mentioned in the previous sub-chapter is the division into two categories: *the centre* or focus, and *the periphery*. In an every day situation, as for example walking down the street, my centre of consciousness, its focus, is on the catastrophic love life of the friend I am going to meet. However, just outside this centre I am, more peripheralcaly, conscious of not bumping into other people walking against me. Even more peripheralcaly I may be aware of the sound of the cars passing by at high speed, and at the outer limit of my consciousness I am aware, but without thinking of it specifically, what day it is and in what city I am. This horizontal or attentional dimension of consciousness, must be contrasted to a vertical conscious-not conscious dimension. The vertical dimension of the mental consists of the conscious and the unconscious. As discussed in the previous section consciousness is regarded as the central mental notion by the biological naturalists. Their conception of the unconscious can be stated in one line: Unconscious states are not mental, if they are not potentially

conscious. There is a paradoxical resemblance to the behaviouristic account of mental states as dispositions to behave. Biological Naturalism regards unconscious mental states as unreal if they in some way or another are not *dispositions for consciousness.* The unconscious states that are not potentially conscious are nothing more than blind neurophysiological processes.

Definitionally there is no problem; those unconscious states that in principle are unable to become conscious are not mental, they are objective neurophysiological processes. However, when applying the distinctions on a practical example as the placebo effect, things get complicated. Is the placebo effect something that is potentially conscious, making it a mental phenomenon? On the one hand, "no". It seems meaningless to speak of a conscious placebo. If I am conscious that the medicine I am receiving is a placebo I assert that the the doctor-patient relationship will be radically changed and the placebo effect not initiated[113]. It is a necessary condition that the patient believes in the placebo treatment. In other words he must be unconscious about the lack of, for example, pharmacological effect. On the other hand, in the placebogenic situation one is conscious of the clinical setting, and of the nervousness and anxiety often associated with the disease. If a placebo effect is initiated, one is also conscious of the decrease of pain or discomfort, or other symptoms that made a visit to the doctor necessary. One is conscious of the clinical setting possibly

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113 I am awere of the frequently quoted article by Park, LC & Covi, L. Nonblind Placebo Trial. Arch. Gen. Psychiat 1965;12:336-45. Though they conclude that the placebo effect can be initiated in patients specifically being told that they recieve a placebo, I think the design of the trial is methodologically problematic, and am sceptic about the generality of their conclusion .

initiating a placebo effect, and of the effects themselves, but without being conscious of the placebo effect as such. In this sense one is conscious of the effect and of the cause but not of the real causal connection. Consciousness has two aspects. The on-off aspect and the positive phenomenological aspect. The placebo effect rests firmly on the first on-off aspect. It is a necessary component of the placebogenic complex that a patient is conscious. However, the phenomenological aspect is more complicated. The placebogenic complex implies an interaction between the patient, doctor and the clinical setting. This interaction presupposes some kind of mental black box with at least a partly unconscious causal relation between the conscious input (placebogenic complex) and the conscious output (the placebo effect). The black box is thus situated on both sides of the line between consciousness and unconsciousness.

This analysis raises two important questions. Firstly what makes the unconscious states conscious? The second one is what is the causal relation between the non-mental and the mental. The last one a variant of the old interactionist problem, what is the causal nature between the mind and the body. The biological naturalists rest on the excommunication of that problem from the field of philosophy, and would simply answer that the ontology of the non-mental is neurophysiological. However, the first question must be answered. What is aimed at is the ontological framework for a psychology that operates only with the two basic notions of neurophysiology and consciousness. A minimal demand to this framework is that it makes the general interaction between the unconscious and the conscious comprehensible. In general we can control our centre of consciousness to a certain extend. However, we

all have experienced difficulties with concentration, or experienced idiosyncrasies. We all have had sudden bursts of intuitions. The interesting question is whether there is some way of explaining the causal relations inside the blackbox, placed over the line of the unconscious.

A general account of the relation between consciousness and unconsciousness would be of great interest to psychology, and a specific account of the causal interactions leading to the placebo effect, would be of great interest to medicine. Such a project is needed if biological naturalism is to defend itself from sceptical critics, and claim to have solved not only the general mind-body problem, but also the specific therapeutical interaction between mind and body known as the placebo effect. However, such an analysis implies a frontal attack on the Freudian notion of the subconscious.[114] I will not comment on whether such a project can succeed, but emphasise that though biological naturalism is a plausible and in many ways intriguing theory, it has unsolved problems, problems that if not addressed make the claimed solution to the mind-body problem less palatable.

A hard core materialist would probably regard biological materialism as just another variant of property dualism, taking credit from the scientific approach, but not being coherent as it operates with the irreducibility of mind. A dualist would probably regard it as materialism in disguise, and not accept the mind as a phenotype among other biological phenotypes. A dry academical

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[114] See note 104: p.167-73

reply would be that biological naturalism does not solve anything, it illustrates the paradoxical nature of the mind-body problem, and then exports the problematic interaction to another intellectual discipline: neurophysiology. However, if the critic intends to be more comprehensive, one possibility is to focus on the epiphenomenalistic tendency in biological naturalism. The mind is on several occasions characterised as an emergent feature of the brain, and compared to solidity as an emergent feature of ice[115].The problem of emergent features in nature generally is that the emergent features do not causally affect the underlying systems, as for example the hardness of a stone does not affect the atoms. Conscious states causally effect bodily functions, as when I decide to lift my arm. Instead of using the emergent property analogy, an alternative strategy is to use the computer analogy. The causal interaction between the "hardware of the brain" and the "software of the mind" is simpler to explain. However, this does not affects the overall project of biological naturalism. The special conscious properties of the mind could be seen as a special "biological program", and instead of a neurophysiological research program there would be a research program within cognitive science. The functionalistic analysis of a program's causal dependence and functional independence of a hardware is, as I see it, very close to the distinction between causal and ontological reduction.

By arguing that the interactionist complexity is not a philosophical but a neurophysiological problem biological naturalism has a strategy that avoids the main philosophical critique of

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115 Ibid: for example p. 14 or p. 112

interactionistic dualism. In that sense biological naturalism can be regarded as a theory that provides a framework for the understanding of the placebo effect. It has the explainatorical capacity of the classical property dualistic theories, but cannot as easily be criticised. It is a theory of mind that simultaneously gives credit to the mental character of the placebo effect and insists that the placebo effect is a neuro-physiological phenomenon. However, biological naturalism has unsolved problems of its own. It has some tendencies to epiphenomenalism, but more important, biological naturalism conflicts with Freudian psychology on important matters, for example, the relation between the conscious and the unconscious. Before the mind-body problem can be heralded as solved, or reduced to a philosophical pseudo problem, biological naturalism has to address its critics comprehensively.

Conclusion

The clinical example in the first pages of the thesis mentioned a Dr. Pascal, who thought "a placebo is a strange thing." Without much reflection Dr. Pascal follows a common inclination in medicine not to distinguish sharply between "the placebo" and "the placebo effect". According to this inclination the placebo effect is simply the effect of a placebo. However logical this may sound it is none the less erroneous.

The placebo effect is a much more complex and general phenomenon than the placebo. A placebo, for example, a sugar pill, has no pharmacological effect whatsoever that can explain why, under certain conditions, it is effective as an analgesic. The explanation given to speculators like Dr. Pascal, is that the placebo pill serves as a symbolic token of the healing process, a material point of focus in a doctor-patient relation that in it self is non material and interpersonal. Theories and hypothesis of the causal mechanisms of the placebo effect have been put forth but with

little success. Some elements of the placebo effect have been explained as conditioning, and the analgesic effect has been associated with internal opoid secretion. The problem of the initiation of a placebo effect, however, is not addressed by the illumination of pits and parts of the causal network culminating in the placebo effect. The reached consensus is that the clinical setting in general and the doctor-patient relation specially are the basic elements in the initiation of the placebo effect. The corporeal changes that the placebo effect represents are initiated by the patients interpretation and experience of the clinical setting. To emphasise the difference between placebo and placebo effect I introduce the term placebogenic complex. A placebogenic complex initiates, or causes, a placebo effect, and consists of a triangular relation between a patient, a healing person, often a doctor, and the clinical setting in which the therapeutical encounter takes places. The clinical setting is not a passive form of the meting between doctor and patient, it is the background on which the doctor-patient relationship is profiled and characterised. The clinical setting contains the conceptual apparatus that enables a person to cope with disease. The clinical setting represents a dissonance room in which the symbolic nature of, for example, the doctor role is given full importance. The placebo as a pill, as a token, can play a part of the placebogenic complex, but is not a necessary part of it. A institutionalised meeting between a patient and a doctor resulting in nothing more that a structured interview can initiate a placebo effect. A placebo on the other hand can never stand alone, it is always part of the broader placebogenic complex.

The general muddled understanding of the interaction between a placebo and the placebo effect is not the only dimension of the placebo debate that is opaque. It is almost symbolic that even the name given to the therapeutical phenomenon in question,"placebo", is a sham, an error. The original Greek sentence from the 116th psalm in the Septuagint Bible, meaning "I shall walk", was mistranslated into the Latin "I shall please". There are several reasons for the chaotic way the term "the placebo effect" is used. One reason is that the empirical material on which a characterisation of the range and size of the placebo effect is not as certain as often assumed. Another reason is that the causal mechanisms of the placebo effect, though describable in general terms, are not known in any detail. In continuation, the causal theory that can be presented is not a classical scientific theory, but a theory in medical humanities. The placebo effect puts strain on several founding notions and assumptions of scientific medicine, both at an epistemological level, regarding the notions of causality, disease and therapy, but also on the metaphysical level regarding the nature of man: the status and relation of mind and body.

The scientific medical model is the term I use to concentrate the heterogeneity and diversity of contemporary medical science into a structure that is possible to describe and analyse. I regard the scientific medical model as consisting of two founding positions, the Bio-mechanical and the Clinico-empirical position. Both share the basic characterisation of scientific medicine as "realism under empirical control", however on two important axis they differ in priorities. The first axis concerns what is regarded the proper level of scientific pursuit. The bio-mechanical position is primarily

ontologically focused on the Error-in-the-machine-analogy whereas the Clinoco-empirical position is primarily is empirically concerned. The second axis touches on the relation between science and therapy. The Bio-mechanical position is primarily oriented towards biological science, and regard therapy as something that, at least to a large extent, can be deducted from biology. The Clinico-empirical position is, as the name indicates, orientated towards clinical science, and regards therapy as something that never automatically can be deduced from any theory.

One of the questions I asked myself in the beginning of the thesis was "what are the implications of the placebo effect for the scientific medical model?" That the patients perception and interpretation of his situation can affect the course of a disease and change bodily symptoms is counter to the basic concepts of the bio-mechanical position. The placebo effect is impossible to enframe in a simple one disease-one cause-one therapy structure. The multicausal placebo effect is difficult to harmonise with the causality concept rooting back to Newton and Bernard. That there exists a therapy that is initiated by the mental interpretation of the patient opposes the Bio-mechanical ideal of therapy, being a pharmacological or surgical intervention and correction of an Error-in-the-machine. It is apparently paradoxical that the placebo effect represents an anomaly to the Bio-mechanical position, when one reflects on the fact that the placebo pill, or more generally the placebo as a token symbol, is a distorted reflection of the Bio-mechanical position. In a way it is the Bio-mechanical position turned 180 degrees. The idea of a placebo could probably not have been developed without the basic notions of the Bio-mechanical

position, and one of the important features of the placebogenic complex is that the patient beliefs he is receiving non-placebo treatment. The placebo as an sham treatment is a theatrical "medical lye"[116], a Bio-mechanical doctor, have to oppose, because of its airy content, but which nonetheless share the form of the "proper" treatment. The placebo effect, on the other hand, does not even share the form of the ideal Bio-mechanical therapy. If scientific medicine was equivalent to the Bio-mechanical position the implications of the placebo effect would be dramatic, however, the Scientific medical model contains a second position: the Clinico-empirical position.

The placebo effect corresponds on important areas to the concepts of the Clinico-empirical position. Most important is that the placebo effect as a multicausal phenomenon can be framed in terms of inus-factors. Also the pragmatic concept of therapy and the nominalistic disease conception correlates with the placebo effect. The placebo effect is a phenomenon that on important areas reflect the concepts of the Clinico-empirical position. However, there are two features of the placebo effect that the Clinico-empirical position has to address. The first regards the practical therapeutical implications of the placebo effect. The second regards the possibility of designing a trial that can quantify the placebo effect. Our knowledge of the specific factors in the placebogenic complex are very limited, and, at present, not sufficient for a therapeutical recommendation of how to behave as a physician if one wants to enhance a placebo effect. At present the rules of thumbs that can be mentioned are

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116 Plato, The Republic: 389 b-c.

not more sophisticated than a general advice to be enthusiastic and self assured, and to be aware that anxious patients are prone to a placebo effect. The therapeutical implications of the placebogenic complex are promising if the rules of thumbs can be specified more.

The second problem is the most serious. The concept of placebogenic complex implies that it is impossible to design a clinical trial that contains a control group where a placebo effect cannot be initiated. One can design a trial divided in placebo maximising and minimising groups, but the precise quantification of the size of the placebo effect will be associated with a principle uncertainty. That it is impossible to measure the placebo effect in it self is a problem for the Clinico-empirical position. On the one hand the clinical implications of the placebo effect are so promising that it makes the phenomenon interesting, on the other hand is the empirical substantiation handicapped by the lack of a proper placebo trial. This is in a way paradoxical, because the notion of placebo effect, as understood today, is born out of the same clinical scientific methodology that emphasises the necessity of exact clinical trials. The terminology of the paradigmatical double blind trial has placebo effect high on the list, the control group is even sometimes called the placebo group. The notion of placebo effect associated with the double blind trials is a negative one, what is measured is the pharmacological or surgical effect of a treatment, and the placebo effect is regarded as a very important phenomenon, but a bias, not as a therapeutical effect in it self. The paradox of the Clinico-empirical position is that the more precise the measure of classical medical treatments are, the more important is the placebo effect as a potential bias, however, it is

impossible to measure the placebo effect positively, and thus make a smooth empirical transformation of the placebo effect from a bias to a therapeutical phenomenon. Though the placebo effect is born out of the Clinico-empirical position and in many ways corresponds to its basic notions, the lack of a specific placebo measuring trial is a puzzle. I use the Kuhnian term puzzle consciously because I do not regard the problem of the Clinico-empirical position as big enough to represent more than a challenge. The implications of the placebo effect on the Scientific medical model is primarily that the tension between the Bio-mechanical position and the Clinico-empirical position is intensified and illuminated. The placebogenic complex places the placebo effect in the context of medical humanities, through its emphasis on the symbolic nature of token placebos, the importance of doctor-patient communication and the clinical setting. The strong association between the placebo effect and the Clinico-empirical position places the placebo effect, with equal solidity, within the context of the Scientific medical model.

The dual characterisation of the placebo effect as both a scientific and humanistic phenomenon parallels the classical dualistic characterisation of the nature of man as consisting of two fundamentals: body and mind. Discussions about the status of the mind in medicine often creates uneasiness, especially when the discussion focuses on the mind's influence on disease.This is understandable when one thinks about the fact that the mind-body problem has occupied philosophers for centuries. Medical terminology operates with a strict distinction of body and mind by using the analogous terms psyche and soma. The interaction between the psyche and soma is acknowledged, for example

through the acceptance of psycho-somatic diseases, but only at an epistemological level. The terminology is regarded as a heuristic device that enables physicians to categorise and handle diseases that operates on the brain. It is silently assumed that when our knowledge of the mechanisms of the brain is good enough this terminology will be abandoned. At an ontological level the medical position is monistic and materialistic. The interactionistic dualism roots back to Descartes. The materialistic position is born out of a scientific world view and is the contemporary dominant theory of the mind, not only amongst physicians but also amongst philosophers.

Though there is a dominant materialistic theory of mind, the mind-body problem is not solved. The materialists are unable to explain the experience of mental phenomena, for example the subjective character of experience. The dualists, on the other hand, are unable to give an account of how the two radically different entities of mind and body interact. The placebo effect does not in general change this pattern. An interactionistic dualistic theory will have no difficulty explaining the placebo effect, and the different materialsitic theories are unable to do so. However, the dualists can still not explain how body and mind interact, and are vulnerable to the attack from the materialists, whose strategy it is to reduce the apparent mental phenomena to bodily functions. What makes the placebo effect special in the mind-body problem is that the placebo effect is not only a mental phenomena, it is also a central part of clinical science. The placebo effect cannot be reduced without at the same time reduce medical science to the Bio-mechanical position. A reduction that most scientific materialsist would oppose because

this would mean a regression to a scientific method practised half a century ago. The implications of the placebo effect on the mind-body problem is that the true paradoxical nature of the problem is emphasised. By being simultaneously scientific and mental the irreducibillity of the placebo effect has to be accepted, even by materialists.

The mind-body problem has been discussed as a serious philosophical problem since Decartes without any solution yet at sight. Possibly it is unsolvable; however, the American philosopher John Searle has recently presented a theory, biological naturalism, that fundamentally opposes the way the mind-body problem is formulated. Sometimes complex philosophical problems are Gordic knots, not because they are to complicated for human intelligence, but because the assumptions, implemented in the way the question is asked, are wrong. It is difficult to characterise biological naturalism as materialism or dualism, because features from both categories are present to a large extent. On the one hand biological naturalism insists that there is no "mind-stuff". The material basis of our consciousness is our brain. On the other hand biological naturalism opposes the ontological reduction of consciousness to the brain. That consciousness causally can be reduced to brain function does not imply that it can be reduced ontologically. Consciousness is an irreducible higher function of the brain. So far the problem biological naturalism has to address is how the brain and consciousness interact. This problem is a variant of the classic dualistic predicament. The response given, however, is not classic.

The interactionalistic problem is regarded as not necessarily a philosophical problem. For centuries the interactionistic problem has been regarded as a relevant philosophical question to ask, but many ancient philosophical problems have later dissolved themselves, or been solved by science, for example, the philosophical analyses of electromagnetism before Maxwell's equations. Biological naturalism regards the interactionistic problem as a problem analogous to electromagnetism prior to Maxwell, and a problem that neorophysiology is best equipped to solve. By not accepting the classical problem of the dualistic position biological naturalism has a strategy that avoids immediate refutation. Whether biological naturalism is the "solution" to the mind-body problem is doubtful, however, intrinsic problems with the theory have to be addressed. For one thing there are tendencies to epiphenomenalism. Secondly, the discussion of the relation between the mental, the consciousness and the subconscious has to be more comprehensive.

Regardless of its potential problems biological naturalism is an interesting theory with regard to the placebo effect because it insists on the irreducibillity of the mind or consciousness at the same time that the theory is anchored in a scientific world view. The placebo effect presents the exact same characteristics, it is basically a mental phenomenon, but also an unavoidable clinical scientific notion. Biological naturalism provides a broad philosophical framework for the understanding of the relation between mind and body, that simultaneously acknowledges the scientific and mental aspects of the placebo effect.

The sharp distinction between medical science and medical humanities cannot be uphold when confronted with the placebo effect. Karl Marx wrote in the Thesis of Feuerbach that the role of philosophy was not to interpret the world but to change it. The force of medical science is that it enables us to change unwanted pathological conditions. Medical humanities has been regarded as a passive form in which the scientific therapy took place. The placebo effect demonstrates that the form of the doctor-patient relationship has an autonomous therapeutical component. The role of medical humanities is not just to interpret, but to actively engage therapeutically. A physician who does not recognise the therapeutical implications of the clinical setting and the doctor patient relationship does not only lack humanistic qualities, but is, as well, a bad clinical scientist.